EDAN INSTRUMENTS, INC.

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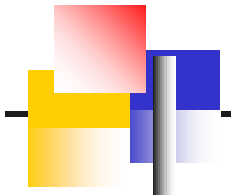

SE-1200/SE-1200 Express

Electrocardiograph

User Manual

Manual Ver: V1.2
Release Date: Dec. 2008
Part Number: MS1R-106764-V1.2

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Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

NOTE: This device is not intended for home use.

⚠WARNING⚠: This device is not intended for treatment.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

Using This Label Guide

This guide is designed to give key concepts on safety precautions.

⚠WARNING⚠

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE: A NOTE provides useful information regarding a function or a procedure.

Revision History

Date	ECO#	Version	Description
2007.08		V1.0	1st edition
2008.08	ECO-QR-8029	V1.1	Amend battery specification
2008.12	ECO-SE-8031	V1.2	Upgrade Software

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1 Safety Guidance

In order to use the electrocardiograph safely and effectively, avoiding possible dangers caused by improper operations, please read through the user manual and be sure to be familiar with all functions of the equipment and proper operation procedures before use.

Please pay more attention to the following warning and caution information.

1.1 Safety Warnings

⚠WARNING⚠:

1. The electrocardiograph is provided for the use of qualified physicians or personnel professionally trained, and they should be familiar with the contents of this user manual before operation.
2. Only qualified service engineers can install this equipment, and only service engineers authorized by EDAN can open the shell.
3. The results given by the equipment should be examined with respect to the overall clinical condition of the patient, and it can not substitute for regular checking.

⚠WARNING⚠:

4. **EXPLOSION HAZARD**-Do not use the electrocardiograph in the presence of flammable anesthetic mixture with oxygen or other flammable agents.
5. **SHOCK HAZARD**-The power receptacle must be a hospital grade grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet.
6. If the integrity of external protective conductor in installation or arrangement is in doubt, the equipment should be operated by using a built-in rechargeable battery.
7. Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.

8. This equipment is not designed for internal use and direct cardiac application.

⚠WARNING⚠:

9. Only patient cable and other accessories supplied by EDAN can be used. Or else, the performance and electric shock protection can not be guaranteed.
10. Be sure that all electrodes have been connected to the patient correctly before operation.
11. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrode, do not come in contact with earth or any other conducting objects.
12. Electrodes with defibrillator protection should be used while defibrillating.
13. Always use electrode gel with reusable electrodes during defibrillation as ECG recovery will take longer than 10 seconds. EDAN recommends the use of disposable electrodes at all times.
14. There is no danger for patients to use pacemaker. However, if a pacemaker is used, the results given by the equipment may be invalid, or lose the clinical significance.
15. Do not touch the patient, bed, table or equipment while using the ECG together with a defibrillator or a pacemaker.
16. In order to avoid being burnt, please keep the electrode far away from the radio knife while using electrosurgical equipment simultaneously.

⚠WARNING⚠:

17. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1-1. Therefore anybody, who connects additional equipment to the signal input connector or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system

standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.

18. The summation of leakage current should never exceed leakage current limits while several other units are used at the same time.

19. The potential equalization conductor can be connected to that of other equipment when necessary, to make sure that all these equipment are connected with the potential equalization bus bar of the electrical installation.

1.2 Battery Care Warnings

⚠**WARNING**⚠:

20. Improper operation may cause the battery to be hot, ignited or exploded, and it may lead to the declination of battery's capacity. It is necessary to read the user manual carefully and pay more attention to warning messages.

21. Only qualified service engineer authorized by EDAN can open the battery compartment and replace the battery, and the battery of same model and specification provided by manufacturer should be used.

22. Danger of explosion -- Do not reverse the anode and cathode when connecting the battery.

23. Do not heat or splash the battery or throw it into fire or water.

24. When leakage or foul smell is found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

25. When the battery's useful life is over, contact the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

26. Only when the device is off can the battery be Installed or removed.

1.3 General Cautions

CAUTION:

26. Avoid liquid splash and excessive temperature. The temperature must be kept between 5 ºC and 40 ºC while working, and it should be kept between -20 ºC and 55 ºC during transportation and storage.

27. Do not use the equipment in dusty environment with bad ventilation or in the presence of corrosive.

28. Be sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitter or mobile phone etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. are likely to bring electromagnetic interference.

CAUTION:

29. Before use, the equipment, patient cable and electrodes etc. should be checked. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or performance.

30. The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

    a) Inspect the equipment and accessories for mechanical and functional damage.
    b) Inspect the safety relevant labels for legibility.
    c) Inspect the fuse to verify compliance with rated current and breaking characteristics.
    d) Verify the device functions properly as described in the instructions for use.
    e) Test the protection earth resistance according to IEC/EN 60601-1: Limit 0.1 ohm.
    f) Test the earth leakage current according to IEC/EN 60601-1: Limit: NC 500 uA, SFC 1000uA.
    g) Test the patient leakage current according to IEC/EN 60601-1:

Limit: 10 uA (CF).

h) Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC/EN 60601-1: Limit: 50uA (CF).

The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

31. Ruptured fuse must only be replaced with the same type and rating as the original.

32. The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.

33. This electrocardiograph can not be directly applied to the heart.

34. Federal (U.S.) law restricts this device to sale by or on the order of a physician.

1.4 Cleaning & Disinfection Cautions

CAUTION:

35. Turn off the power before cleaning and disinfection. If mains supply used, the power cord should be drugged out of the outlet also. And prevent the detergent from seeping into the equipment.

36. Do not immerse the unit or patient cable into liquid under any circumstances.

37. Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.

38. Any remainder of detergent should be removed from the unit and patient cable after cleaning.

39. Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.

2 Introduction

12-channel electrocardiograph gathers 12 leads simultaneously, and carries out visual display of operation menu, ECG parameters as well as electrocardiogram.

12-channel waves can be viewed on the LCD (liquid crystal display) screen simultaneously, and it can be recorded by high-quality thermal recorder.

Manual, auto, rhythm or R-R work mode can be chosen conveniently.

Either mains supply or built-in rechargeable Lithium battery can be used as power.

With a high resolution thermal recorder, a 32-bit processor and a huge capacity memorizer, 12-channel electrocardiograph has advanced performance and high reliability, and the compact size makes it suitable for clinic, hospital and ambulance use.

12-channel electrocardiograph has two models: SE-1200, SE-1200 Express.

Configurations: Main unit, power cord, patient cable, chest electrodes, limb electrodes, thermal recording paper, fuses and lithium battery.

Intended use: The intended use of electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface with ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.

⚠**WARNING**⚠: This equipment is intended for use on adult and pediatric patients only.

⚠**WARNING**⚠: This equipment is not designed for internal use or direct cardiac application.

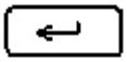
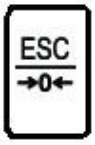
⚠**WARNING**⚠: The results given by the equipment should be examined with respect to the overall clinical condition of the patient. And it can not substitute for regular checking.

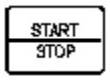
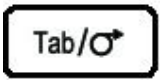
2.1 Function Features

- ♦ Low weight and compact size
- ♦ Multi-language support
- ♦ 12-lead gathered and amplified simultaneously, 12-channel ECG are displayed and recorded simultaneously
- ♦ High resolution thermal recorder, recording frequency response ≤150Hz
- ♦ Flexible recording formats
- ♦ Big keyboard design, separate number and letter keys for easy operation (For SE-1200 Express, touch screen is available)
- ♦ Auto mode, manual mode, rhythm mode, R-R mode optional
- ♦ Convenient system setup and file management operation
- ♦ Auto measurement and auto interpretation optional
- ♦ Hint information for lead off, lack of paper and low battery capacity etc.
- ♦ Built-in rechargeable Lithium battery with high capacity
- ♦ Automatic adjustment of baseline for optimal recording

2.2 List of Symbols

	External output
	External input
	Equipment or part of CF type with defibrillator proof

	Attention – general warning (see accompanying document)
	Potential equalization
	Mains supply
	Battery indicator
	Battery recharging indicator
	Delete key
	Enter key
	Esc key/Baseline Reset key
	Shift key
	Fn key
	Power On/Off key
	COPY key
	MODE key
	SLEEP/WAKE UP key

	START/STOP key
	Tab key/Feed Paper key
	UP/DOWN/LEFT/RIGHT arrow key
	Recycle
P/N	Part Number
	Serial Number
	Date of Manufacture
	Manufacturer
	Authorized Representative in the European Community
	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.
	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life and that this unit was put on the market after 13 August 2005.
Rx only (U.S.)	Federal (U.S.) Law restricts this device to sale by or on the order of a physician

3 General Information

3.1 Top Panel

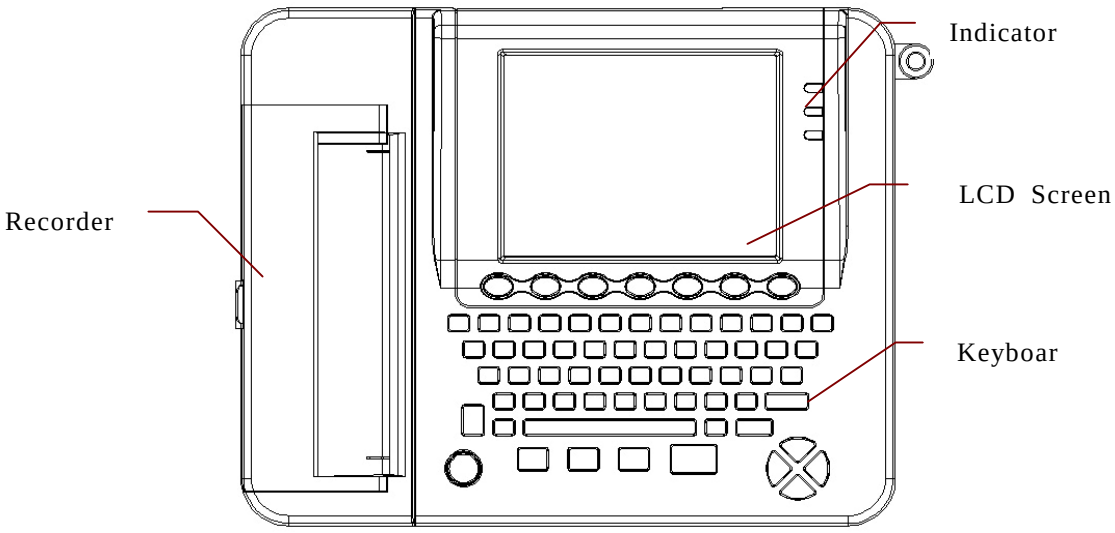


Figure 3-1 SE-1200 Express

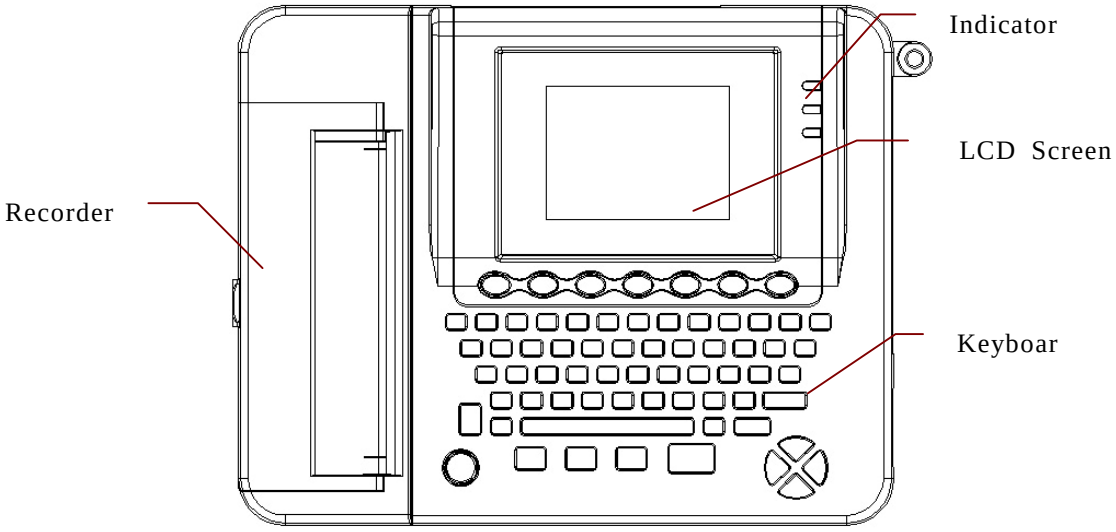


Figure 3-2 SE-1200

3.1.1 LCD Screen

SE-1200: 320×240 dot single color LCD Screen; SE-1200 Express: 800×600 multicolor LCD Screen.

Figure 3-3 SE-1200 Express Main Screen

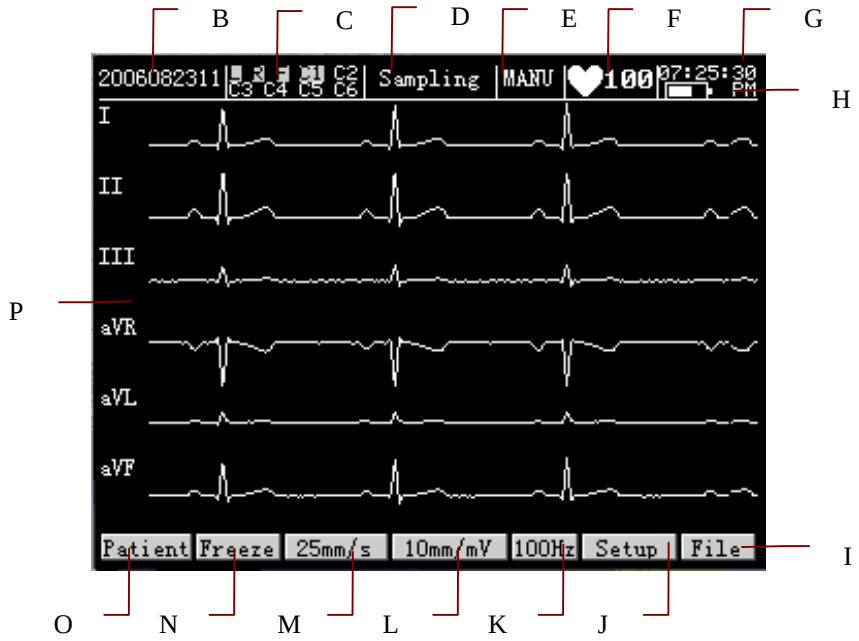


Figure 3-4 SE-1200 Main Screen

	Name	Explanation
A	Name	Patient Name: Within 20 characters
B	ID	Patient ID: Within 10 characters
C	Hint Information 1	Including “Demo Display”, “Modu Error”, “Overload” ,“Lead Off”(When the leads are off, they will be shown in black words on yellow background in the SE-1200 Express, while in the SE-1200, they will be shown in black words on white background .)
D	Hint Information 2	Including “No Paper”, “Paper Error”, “Battery Weak”, “Sampling”, “Analyzing”, “Recording”, “Doing”, “Learning”, “Transmitting”, “Transmit Fail”, “Detecting”, “Memory Full”, “U Disk”, “USB Printer”, “Lead Off”
E	Work Mode	Manual, Auto, Rhythm or R-R
F	Heart Rate	Actual Heart Rate
G	Current Time	Refer to Chapter 5.9.10
H	Battery Symbol	Identify the current capacity of the rechargeable battery
I	File	Enter File Manage Window; Refer to Chapter 5.10
J	Setup	Enter System Setup Window; Refer to Chapter 5.9
K	100Hz	EMG Filter: 25Hz, 35Hz or 45Hz Lowpass Filter: 75Hz, 100Hz or 150Hz **Note**: This setup can’t be saved if it is modified on the Main Screen.
L	10mm/mV	Gain: 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 10/5 mm/mV or AGC **Note**: This setup can’t be saved if it is modified on the Main Screen.
M	25mm/s	Paper Speed: 5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s or 50mm/s **Note**: This setup can’t be saved if it is modified on the Main Screen.
N	Freeze	Freeze ECG waveform; Refer to Chapter 5.3
O	Patient	Enter Patient Information interface; Refer to Chapter 5.9.6
P	ECG waveform	Display ECG waveform

3.1.2 Keyboard and Keys

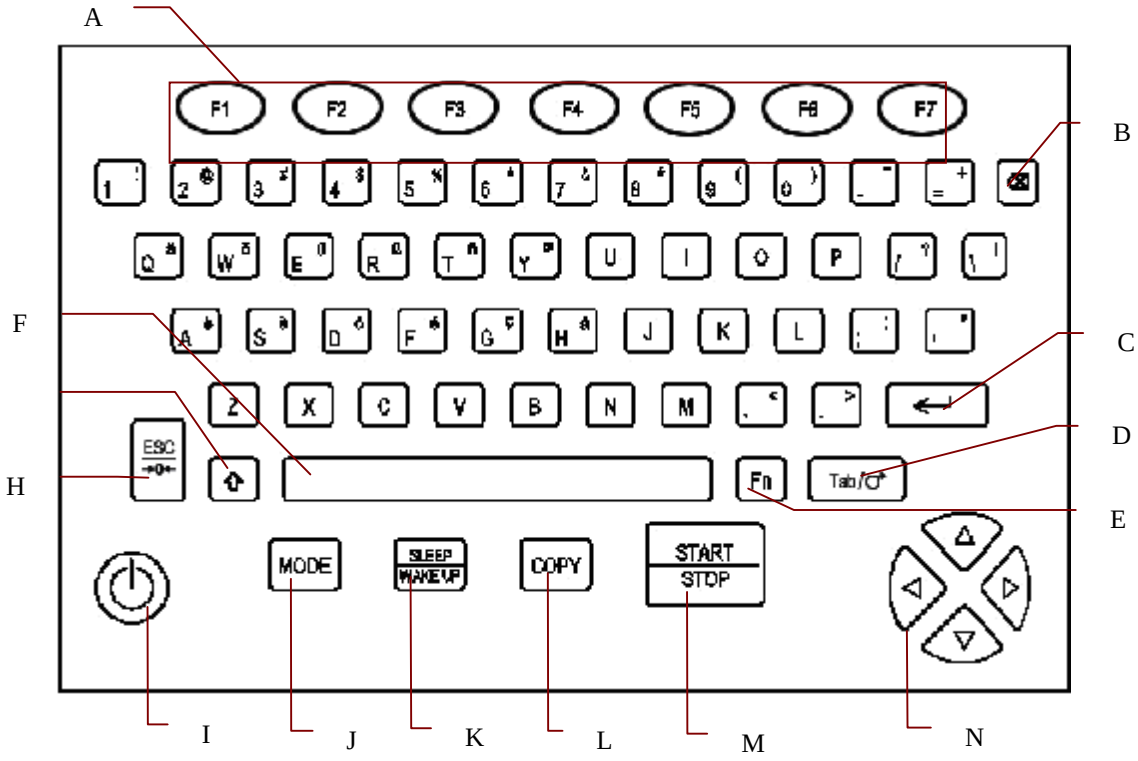


Figure 3-5 SE-1200/SE-1200 Express Keyboard

	Name	Explanation
A	Function Key	Selecting menu functions on screen
B	Delete	Deleting characters
C	Enter	Confirming operation
D	Tab	Moving cursor On the Main Screen interface, pressing the Tab key to feed the recording paper to the next paper marker, (when **Paper Marker** is set as **Yes**)or get to 2.5cm(when **Paper Marker** is set as **No**), pressing the Tab key again to stop feeding.
E	Fn	Used for entering special characters
F	Spacebar	Inserting spacebar
G	Shift	Used for entering capital letters Shift+Tab=BackTab
H	Esc	Canceling operation Draw the baseline to zero quickly in the case of baseline drift
I	Power On/Off	Power-on/Power-off
J	MODE	Selecting Work mode: Manual, Auto, Rhythm **Note:** Only in the Work Mode Setup interface can R-R mode be selected.
K	SLEEP/ WAKE UP	Used for resting and wakening electrocardiograph
L	COPY	Reviewing the last ECG data recorded in the Auto mode
M	START/STOP	Start/Stop recording
N	Arrow Keys	Moving cursor (Up, Down, Left, Right) In the Manual Mode or Rhythm Mode, press Up/Down to switch the lead group.

3.2 Front Panel

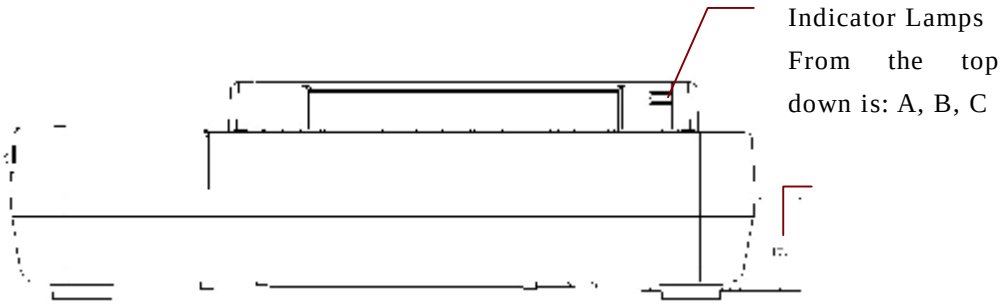


Figure 3-6 SE-1200 Express Front Panel

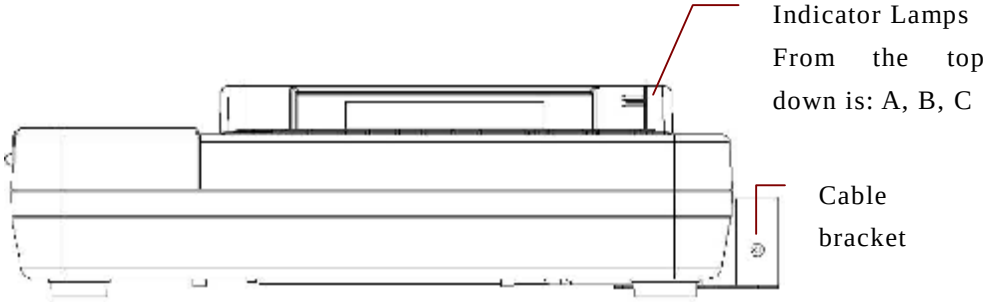


Figure 3-7 SE-1200 Front Panel

1) Indicator Lamp

	Symbol	Name	Explanation
A	~	Mains supply indicator lamp	When the device is powered by mains supply, the lamp will be lit.
B		Battery indicator lamp	When the device is powered by the built-in rechargeable Lithium battery, the lamp will be lit.
C		Battery recharging indicator lamp	When the battery is recharged, this lamp will be lit.

2) Cable bracket(Optional)

Used for supporting patient cable.

3.3 Rear Panel

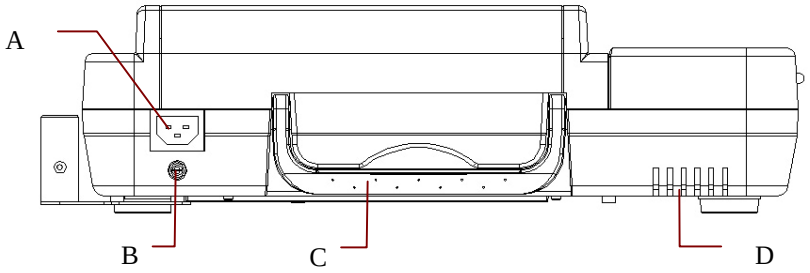


Figure 3-8 SE-1200/ SE-1200 Express Rear Panel

	Name	Explanation
A	Mains supply Socket	~ AC SOURCE: alternating current supply socket
B	Potential Equalization Terminal	⏚ Potential equalization conductor provides a connection between the unit and the potential equalization bus bar of the electrical installation.
C	Handle	Part for people to hold when carrying the device
D	Heat Emission Hole	Path for internal heat emission

3.4 Right Panel

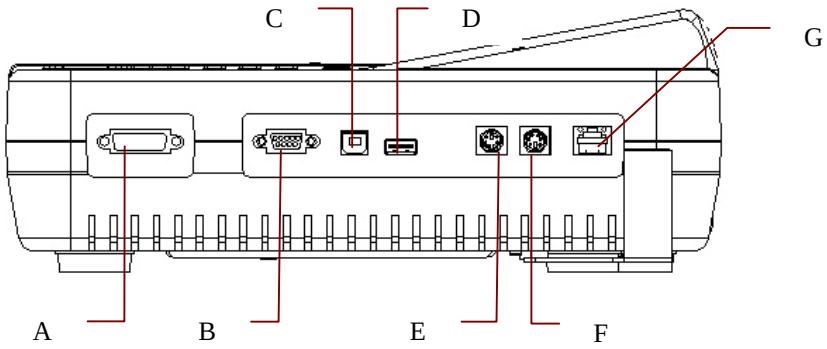
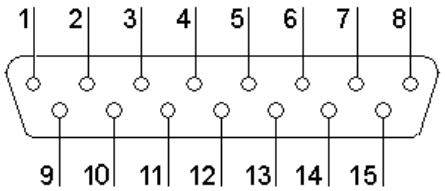


Figure 3-9 SE-1200/SE-1200 Express Right Panel

	Name	Explanation
A	Patient Cable Socket	Connecting patient cable
B	Serial Port 1	Connecting PC
C	USB Socket 1(Optional)	Standard USB socket, connecting PC
D	USB Socket 2(Optional)	Standard USB socket, connecting USB, USB printer recommended by EDAN
E	External Input/Output Socket	Connecting external signal device
F	Serial Port 2	Reserved
G	Net port	Standard net port, connecting PC

1) Patient Cable Socket



: Applied part of type CF with defibrillator proof

⚠: Attention – see accompanying document

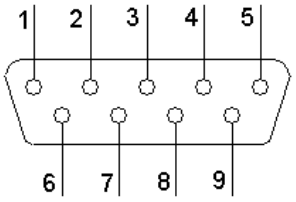
Definition of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	C2 (input)	**6**	SH	**11**	F (input)
2	C3 (input)	**7**	NC	**12**	NC
3	C4 (input)	**8**	NC	**13**	C1(input)
4	C5 (input)	**9**	R (input)	**14**	NC
5	C6 (input)	**10**	L (input)	**15**	N or RF (input)

2) Serial port 1

⚠**WARNING**⚠:

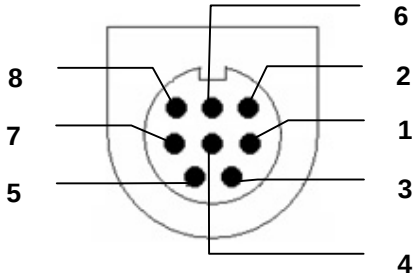
Serial port 1 is 1500V AC isolated intensity and the maximum voltage applied should not exceed +15V DC.



Definition of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	NC	**4**	NC	**7**	NC
2	RxD (input)	**5**	GND	**8**	+12V
3	TxD (output)	**6**	NC	**9**	NC

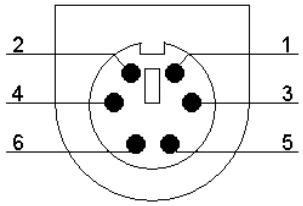
3) Serial port 2



Definition of corresponding pins:

Pin	Signal	Pin	Signal
1	TxD (output)	**5**	NC
2	RxD (input)	**6**	+12V
3	NC	**7**	GND
4	+5V	**8**	GND

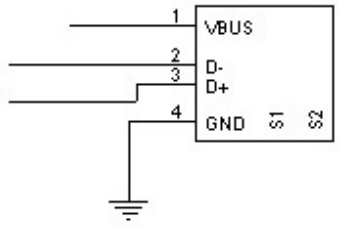
4) External Input/Output Socket



Definition of corresponding pins:

Pin	Signal	Pin	Signal
1	GND	**4**	GND
2	GND	**5**	ECG Signal
3	GND	**6**	ECG Signal

5) USB Socket 1/USB Socket 2 (Optional)



Definition of corresponding pins:

Pin	Signal	Pin	Signal
1	VBUS	**3**	D+
2	D-	**4**	GND

⚠**WARNING**⚠: Only the USB equipment recommended by EDAN can be connected to the USB interface.

⚠**WARNING**⚠:

- Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.
- The summation of leakage current should never exceed leakage current limits while several other units are used at the same time.

3.5 Bottom Panel

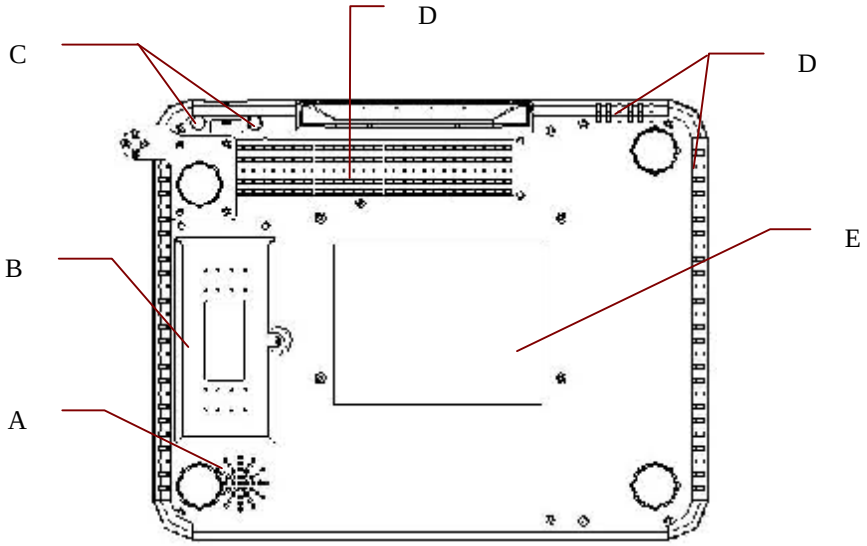


Figure 3-10 SE-1200/SE-1200 Express Bottom Panel

	Name	Explanation
A	Speaker Hole	Path for sound from speaker
B	Battery Compartment	Compartment for Lithium battery
C	Fuse	The specification is : AC100V-240V: T1A; Ø5×20

D	Heat Emission Hole	Path for internal heat emission
E	Label	Position for product information label

1) Battery Compartment

The rated voltage and rated capacity of rechargeable Lithium battery pack are:
SE-1200 Express: Rated Voltage: 14.8V; Rated Capacity: 4000mAh/4400mAh
SE-1200: Rated Voltage: 14.8V; Rated Capacity: 2000mAh /2200mAh/2400mAh

⚠**WARNING**⚠:

Improper operation may cause the battery to be hot, ignited or exploded, and it may lead to the decrease of battery's capacity. Therefore, it is necessary to read the user manual carefully and pay more attention to warning messages.

⚠**WARNING**⚠:

When leakage or foul smell found, stop using the battery immediately. If the leakage liquid gets to your skin or cloth, cleanse it with clean water at once. If the leakage liquid gets into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

⚠**WARNING**⚠:

Only qualified service engineer authorized by EDAN can open the battery compartment and replace the battery. And the battery of same model and specification provided by manufacturer must be used.

⚠**WARNING**⚠:

Only when the device is off can the battery be installed or removed.

Note: If the battery has not been used for two or three months or above, recharge should be done before use the battery again.

2) Fuse

There are two same fuses installed on the bottom of the main unit. The specification is: AC100V-240V: T1A; Ø5×20.

⚠**WARNING**⚠: Ruptured fuse must only be replaced with that of the same type and rating as the original.

4 Operation Preparations

CAUTION:

Before use, the equipment, patient cable and electrodes should be checked. Replace it if there is any evident defectiveness or aging which may impair the safety or performance, and be sure that the equipment is in proper working condition.

4.1 Power and Earthing

WARNING:

If the integrity of external protective conductor in installation or arrangement is in doubt, the equipment should be powered by the built-in rechargeable battery.

Power Supply

The electrocardiograph can be powered by either mains supply or the built-in rechargeable lithium battery pack.

♦ **Mains supply**

The mains connection socket is on the rear panel of the unit. If mains supply is used, connect the power cord to the socket first, and then connect the plug of the cord to the hospital grade outlet.

Rated input voltage: 100V~240V

Rated frequency: 50Hz/60Hz

Rated input power: 70VA

Make sure the mains supply meets the above requirements before power on, and then press **Power ON/OFF** button on the keyboard to power on the unit. Then the mains supply indicator lamp (∿) will be lit.

If the built-in rechargeable battery is weak when mains supply used, it will be recharged automatically at the same time. And both the mains supply indicator lamp (∿) and the battery recharging indicator lamp (⇥▭) will be lit.

♦ **Built-in rechargeable battery**

While using the built-in rechargeable lithium battery pack, turn on the unit

by pressing **Power ON/OFF** button on the keyboard and the battery indicator lamp ( ) will be lit.

The battery symbol will be displayed on the LCD screen. Because of the consumption during storage and transport, the capacity of battery may not be full. If the symbol or and the hint information "Battery Weak" are displayed, which means the battery capacity is weak, please recharge the battery first.

When the capacity of battery is full, SE-1200 can work normally for nearly 2 hours; about 200 ECG of **3**×4+1r can be recorded in the Auto Mode. SE-1200 Express can work normally for nearly 3.5 hours; about 400 ECG of **3**×4+1rhy can be recorded in the Auto Mode.

Please refer to the maintenance section for how to recharge the battery. During recharging the battery, electrocardiograph can be powered by mains supply.

⚠**WARNING**⚠: Potential equalization conductor of the unit should be connected to the potential equalization bus bar of the electrical installation when necessary.

4.2 Loading/Replacing Recording Paper

Two kinds of paper can be used as ECG recording paper. One is Rolled thermal paper, another is folded thermal paper.

Note: When using folded thermal paper, the Paper Roller should be removed.

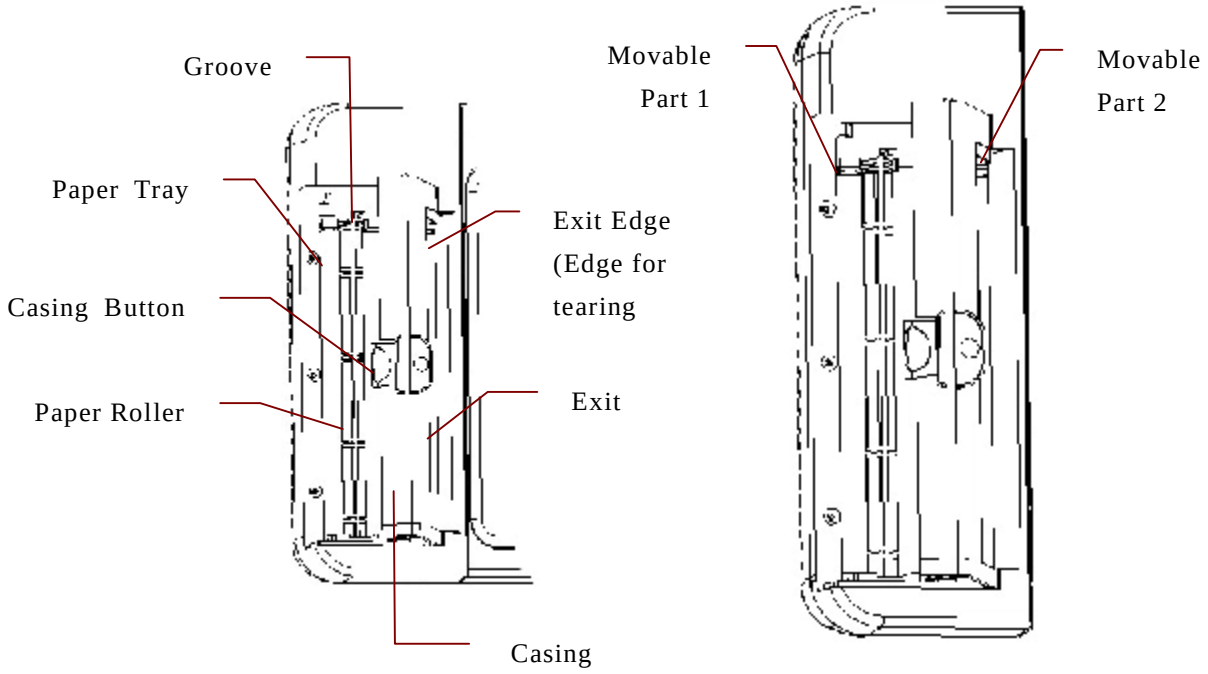
Note: When using the paper of 216mm width, the two movable parts should be removed.

Note: The Exit Edge can help the user tear the recording paper.

CAUTION: Be sure that recording paper, especially rolled paper, should be installed in the center of the recorder, and the edge of paper should be parallel with the edge of casing in the direction of feeding paper, in order to avoid paper deviation and the damage to the edge of paper.

When there is no paper loaded or it reaches the end of paper, hint message "Paper Empty" will be given on the screen. Under this circumstance, recording paper

should be loaded or replaced immediately.



Loading/Replacing Process for Rolled paper:

1) Press the Casing Button downwards with one hand and pull the casing upwards with another hand to open the recorder.
2) Take out the Paper Roller, and remove remainder paper from the roller if necessary;
3) Take off the wrapper of paper roll, and then put through the roller with the paper's grid side facing downward;
4) Place the paper and roller gently in the recorder with the roller pin facing to the groove;
5) Pull about 2cm of paper out from the Exit, and put down the recorder casing;
6) Secure the casing by pressing it firmly.

Loading/Replacing Process for Folded paper:

1) Press the Casing Button downwards with one hand and pull the casing upwards with another hand to open the recorder.
2) Remove remainder paper in the Paper Tray if necessary;
3) Take off the wrapper of folded paper, and then put it in the Paper Tray with the paper's grid side facing right while putting the free end of paper upright;

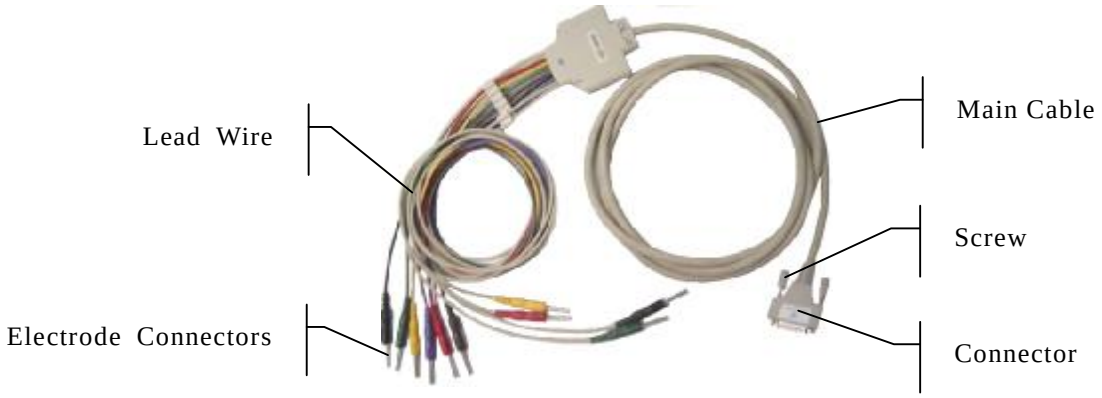
4) Pull about 2cm of paper out from the Exit, and put down the recorder casing;

5) Secure the casing by pressing it firmly.

4.3 Patient Cable Connection

⚠**WARNING**⚠: The performance and electric shock protection can be guaranteed only if original EDAN patient cable and electrodes are used.

Patient cable includes two parts, main cable and lead wires with associated connectors, which can be distinguished from the color and identifier on the connectors.

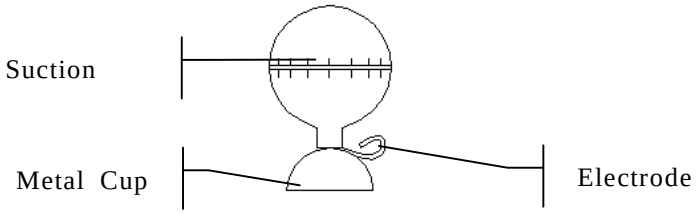


Connecting Main Cable:

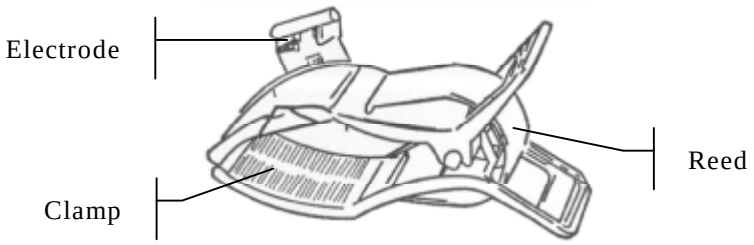
Plug the connector of main cable into the patient cable socket on the right side of the unit according to the direction of arrow on the plug, and then secure it with two screws.

4.4 Electrode Connection

Chest Electrode:



Limb Electrode:



The identifier and color code of electrodes used complies with IEC/EN requirements. In order to avoid incorrect connections, the electrode identifier and color code are specified in Table 4-1. Moreover the equivalent code according to American requirements is given in Table 4-1 too.

Table 4-1 Electrodes and their identifiers and color codes

	European		American	
Electrodes	**Identifier**	**Color code**	**Identifier**	**Color code**
Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Right leg	N or RF	Black	RL	Green
Left leg	F	Green	LL	Red
Chest 1	C1	Red	V1	Red
Chest 2	C2	Yellow	V2	Yellow
Chest 3	C3	Green	V3	Green
Chest 4	C4	Brown	V4	Blue
Chest 5	C5	Black	V5	Orange
Chest 6	C6	Violet	V6	Violet

As the following figure shows, the chest electrodes' positions on body surface are

C1: Fourth intercostals space at right border of sternum

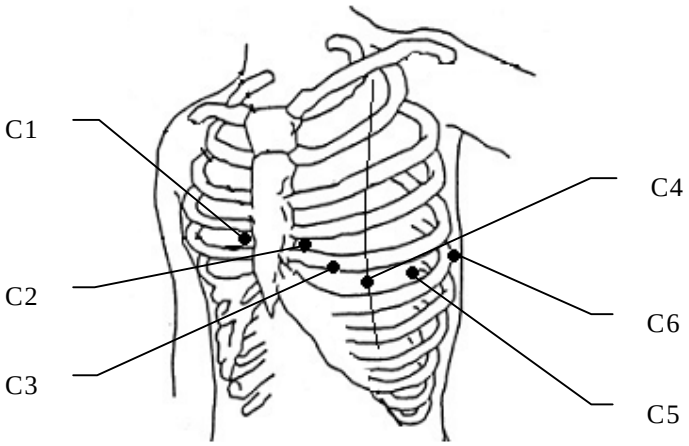
C2: Fourth intercostals space at left border of sternum

C3: Fifth rib between C2 and C4

C4: Fifth intercostals space on left midclavicular line

C5: Left anterior axillary line at the horizontal level of C4

C6: Left midaxillary line at the horizontal level of C4



The contacting resistance between the patient and the electrode will affect the quality of ECG greatly. In order to get a high-quality ECG, the skin/electrode resistance must be minimized while connecting electrodes.

⚠**WARNING**⚠: Be sure that all electrodes have been connected to the patient correctly before operation.

⚠ **WARNING** ⚠ : Ensure that the conductive parts of electrodes and associated connectors, including neutral electrode, do not come in contact with earth or any other conducting objects.

Chest electrode connection:

1) Ensure that the electrodes are clean;
2) Align all lead wires of patient cable to avoid twisting, and connect the associated electrode connectors to corresponding electrodes according to the color and identifier;
3) Clean electrode area on chest surface with alcohol;
4) Daub the round area of 25mm in diameter on each electrode site with gel evenly;
5) Place a small mount of gel on the brim of chest electrode's metal cup;
6) Place the electrode on chest electrode site and squeeze the suction bulb. Unclench it and then the electrode is adsorbed on chest. Attach all chest electrodes in the same way.

Limb electrode connection:

1) Ensure that the electrodes are clean;

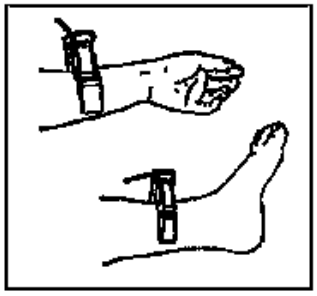
2) Align lead wires of patient cable to avoid twisting, and connect the electrode connectors to corresponding electrodes according to the color and identifier;

3) Clean electrode areas on a short distance above the ankle or wrist with alcohol;

4) Daub the electrode areas on limbs with gel evenly;

5) Place a small amount of gel on the metal part of limb electrode clamp;

6) Connect the electrode to limb, and be sure that the metal part be placed on the electrode area above the ankle or wrist. Attach all limb electrodes in the same way.



4.5 Inspection before Power-On

In order to avoid safety hazards and get good ECG records, the following inspection procedure is recommended before power-on and operation.

1) **Environment**:

- ♦ Check and make sure that there is no electromagnetic interference source around the equipment, especially large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. Switch off these devices when necessary.
- ♦ Keep the examination room warm to avoid muscle action voltages in ECG signal caused by cold.

2) **Power Supply**:

- ♦ If mains power is used, please check whether the power cord has been connected to the unit well, and the grounded outlet should be used.
- ♦ Recharge the battery first when the battery capacity is weak before use.

3) **Patient Cable**:

- Check whether the patient cable has been connected to the unit firmly, and keep it far away from the power cord.

4) **Electrodes**:

- Check whether all electrodes have been connected to lead wires of patient cable correctly according to the identifier and color.
- Ensure that the chest electrodes do not contacted with each other.

5) **Recording Paper**:

- Ensure that there is enough recording paper loaded correctly.

6) **Patient**:

- The patient should not contact conducting objects such as earth, metal part of bed etc.
- Ensure the patient is warm and relaxed, and breathes calmly.

⚠**WARNING**⚠: The electrocardiograph is provided for the use of qualified physicians or personnel professionally trained, and they should be familiar with the contents of this user manual before operation.

5 Operation Instructions

5.1 Switching On

- While using mains supply, firstly connect the power cord, and the mains supply indicator lamp (∿) is lit. Then press **Power ON/OFF** key on the keyboard to turn on the unit. Equipment information, such as manufacturer, device name and version No., will be displayed on LCD screen after self-test. Then electrocardiograph is ready for examination and recording.
- While using built-in rechargeable lithium battery, press **Power ON/OFF** key on the keyboard directly to turn on the unit, and then the battery indicator (▭) is lit. After self-test, electrocardiograph is ready for examination and recording.

5.2 General operation

All the operations including ECG recording, parameter setting and file managing can be implemented by using the keyboard.

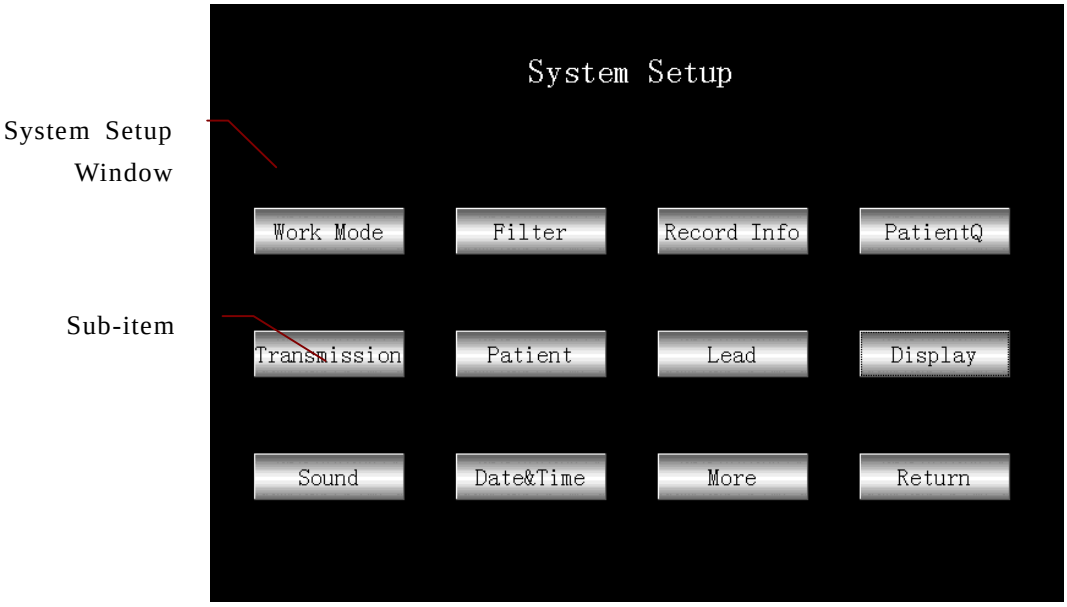
For SE-1200 Express, users can also carry out the operations by using the Touch Screen.

⚠**WARNING**⚠: Do not touch the LCD screen with such sharp things as pencil or pen; otherwise, it will be damaged.

Take these general operations needed when using System Setup Window for example:

(1) Entering System Setup Window

Press the corresponding Function Key of **Setup** on the keyboard to enter the System Setup Window.

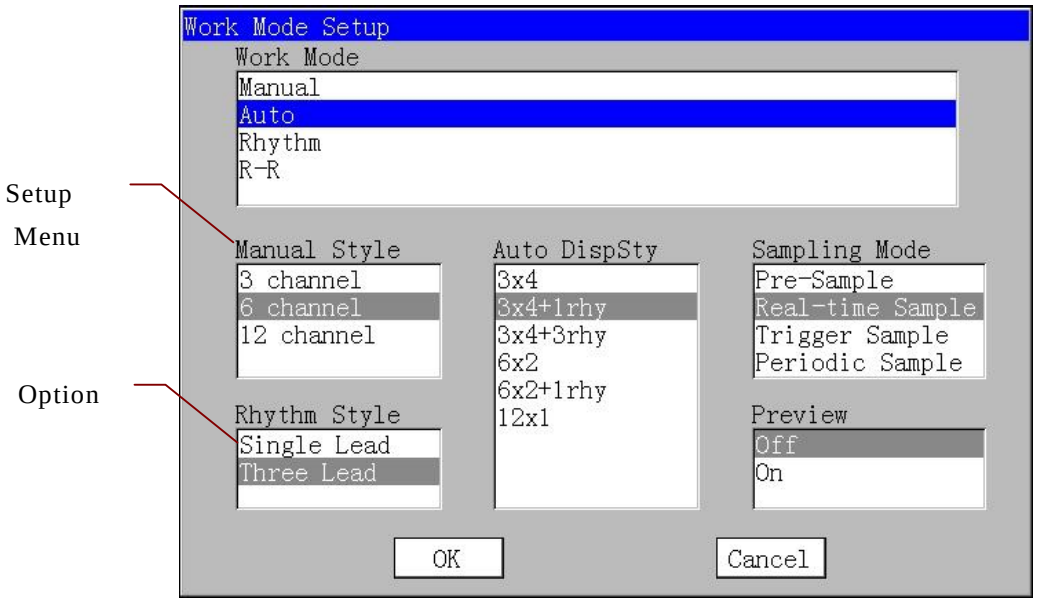


(2) Selecting sub-items in the System Setup Window

In the System Setup Window, press **Up/Down/Left/Right/Tab/BackTab** key to move the cursor to a certain sub-item, and then press Enter key to get into the setup interface of the sub-item.

(3) Sub-item Setup interface

Take the Work Mode Setup interface for example:



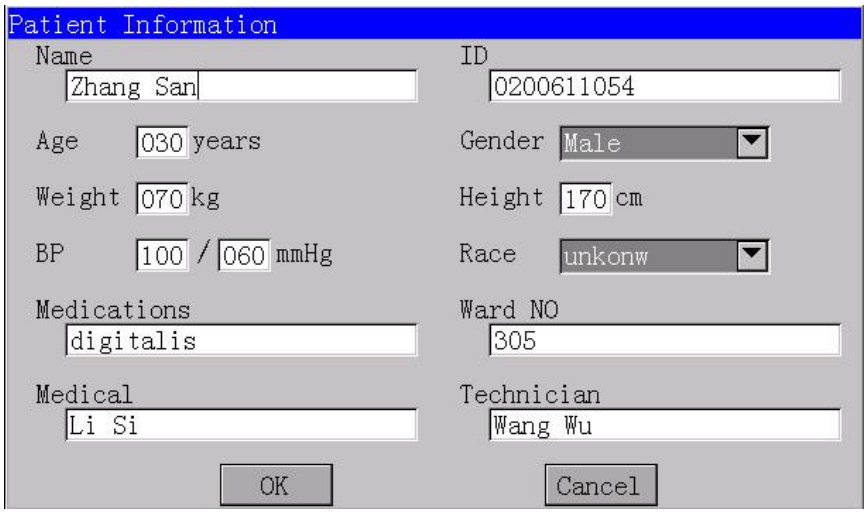
On the Work Mode Setup interface, pressing **Tab/BackTab** key can move the cursor between different Setup Menus; pressing Up/Down key can move the cursor between different options in a Setup Menu; Move the cursor to a certain option, and press Enter key to confirm or Esc key to cancel.

Users can also press Tab key to move the cursor to OK and press Enter key to confirm;

move the cursor to Cancel and press Enter key to cancel operation.

(4) Inputting characters

Take the Patient Information interface for example:



- Press Tab key to move the cursor to Name;
- Press Delete key to delete old information;
- Press the letter keys or number keys on the keyboard to input patient name and press Enter key to confirm.

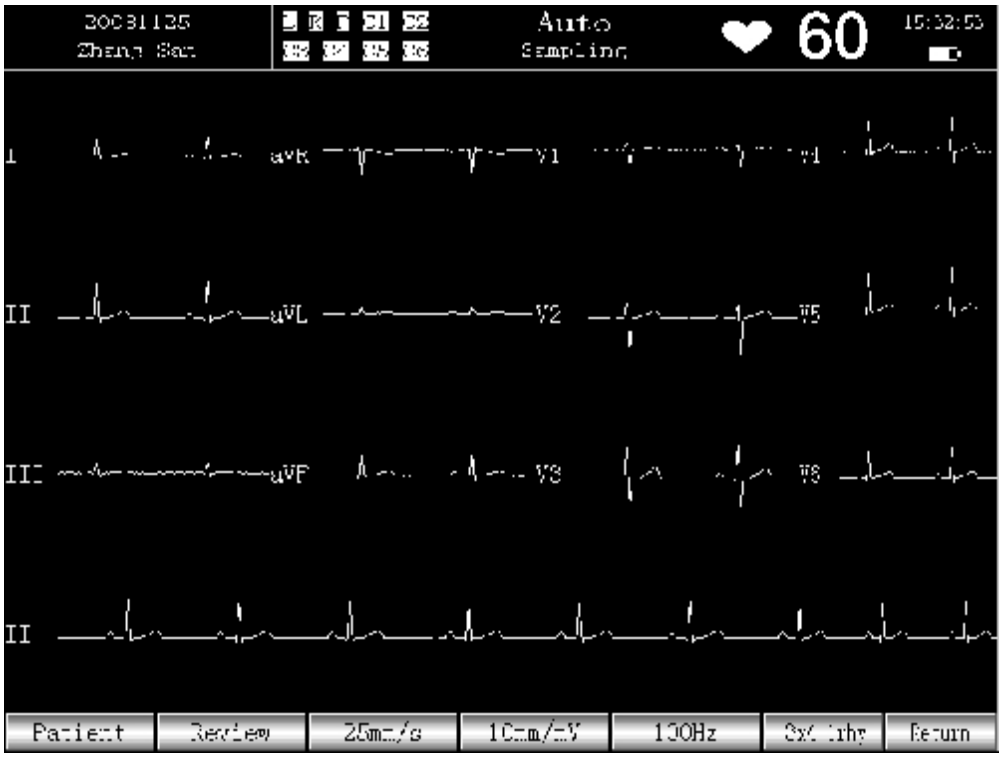
In the File Manage Window, the general operations of selecting ECG files, setting parameters and inputting characters are the same as the content described above.

5.3 Freeze

Users can freeze the ECG wave displaying on the main screen.

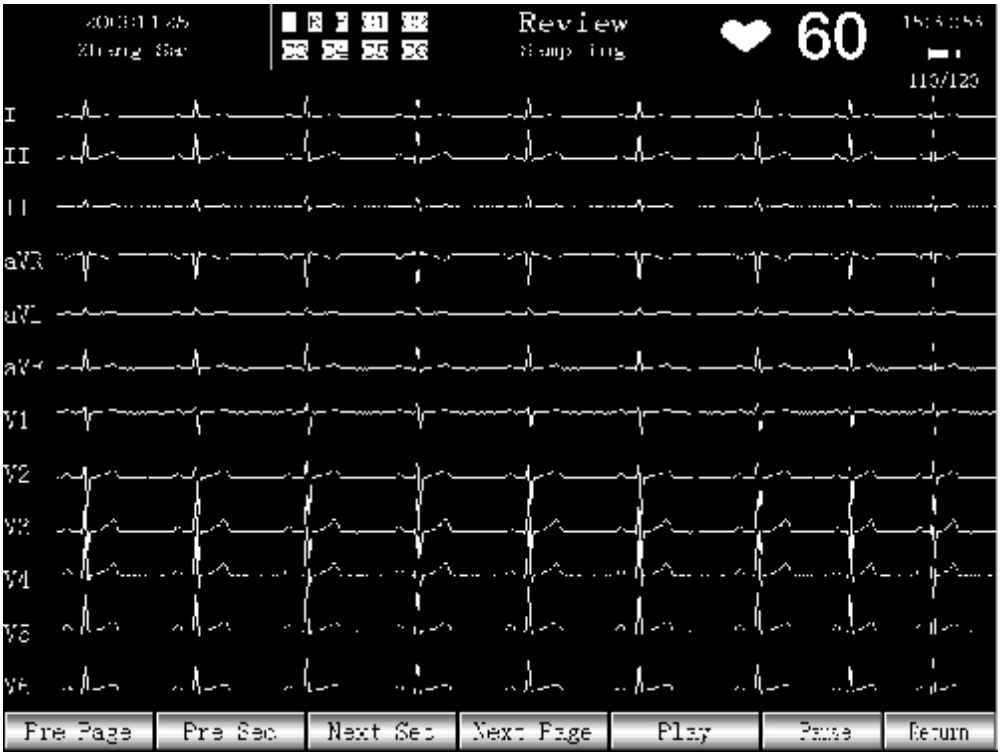
Operation Method:

1) Press the corresponding Function Key of **Freeze** on the keyboard (hereinafter called **Freeze** function key) to freeze ECG wave;



2) On the Freeze interface**,** Press **3x4+1rhy** function key can set the style of recording.

3) Press **Review** function key to review the ECG wave which has been frozen;



4) Press **Pre Page**/**Next Page** function key to turn the pages;
5) Press **Pre Sec**/**Next Sec** function key to view the ECG wave of pre second/ next second;
6) Press **Play** function key to display ECG wave continuously;
7) Press **Pause** function key to stop playing ECG wave;
8) Press **Return** function key to return to main screen;

5.4 Auto Mode

In the Auto mode, the lead groups are switched automatically according to the lead sequence while recording. When the ECG signal of one lead group has been recorded within a certain time, it will be switched to another lead group automatically and begins to record the ECG signal of that lead group. 1mV calibration mark will be recorded at the beginning of recording.

Operation Method:

1) Input patient information before recording;
2) Enter Work Mode Setup interface to select Auto mode, and set Auto Display Style, Sample Mode and Preview;
3) Enter Record Information Setup interface to select Record Control page, and set Record Style, Record Sequence and Record Mode.
4) Enter Lead Setup interface to set Lead Sequence;
5) After finishing setting parameters, exit the System Setup Window;
6) If Preview is set as off, press **START/STOP** key to begin recording. It will stop automatically after a full 12-lead ECG is recorded;
7) If Preview is set as on, press **START/STOP** key to enter the Preview Window. In Preview Window, pressing **Measure** function key can enter the Measure Window, pressing **Diagnosis** function key can enter the Diagnosis Window, pressing **Continue** function key can begin recording, and pressing **Cancel** function key can cancel recording.

Preview Window

Pressing START/STOP again during the course of recording can stop recording.

Note: Whether in the auto, rhythm, R-R or manual mode, Work Mode can not be changed during the course of recording. Stop recording before choosing Work Mode.

5.5 Manual Mode

In the Manual mode, users can determine which lead group needs to be recorded and set the parameters according to different lead group.

Operation Method:

1) Input patient information before recording;
2) Enter Work Mode Setup interface to select Manual mode, and set Manual Style;
3) Enter Lead Setup interface to set Lead Sequence;
4) After finishing setting parameters, exit the System Setup Window;
5) Press **UP** or **DOWN** key to select the lead group to be recorded;
6) Press **START/STOP** key to begin recording;
7) Press **START/STOP** key to stop recording after ECG is recorded.

UP or **DOWN** key can be pressed to switch the lead group during the course of

recording. Pressing START/STOP again during the course of recording can stop recording.

5.6 Rhythm mode

In the Rhythm mode, users can record 60s rhythm-lead ECG waveform in Single Lead Style or 20s rhythm-lead ECG waveform in Three Lead Style.

Operation Method:

1) Input patient information before recording;
2) Enter Work Mode Setup interface to select Rhythm mode, and set Rhythm Style;
3) Enter Lead Setup interface to select rhythm leads;
4) After finishing setting parameters, exit the System Setup Window;
5) Press **START/STOP** key and the sampling time will be counted. When the sampling time reaches 60s in Single Lead Style or 20s in Three Lead Style, it begins to record;
6) It will stop automatically after a full rhythm-lead ECG waveform is recorded.

Pressing START/STOP again during the course of recording can stop sampling or recording.

5.7 R-R mode

In the R-R mode, users can select a lead to record its R-R Histogram, R-R Trend Chart, 180s ECG waveform and all the R-R values.

Operation Method:

1) Input patient information before recording;
2) Enter Work Mode Setup interface to select R-R mode;
3) Enter Lead Setup interface to select a lead in the field of Rhythm Lead 1;
4) Enter Recording Information Setup interface to select the style of R-R Analysis Report;
5) After finish setting parameters, exit the System Setup Window;
6) Press START/STOP key to begin to count the sampling time. When the Sampling Time reaches 180s, it begins to record;

7) It will stop automatically after a full R-R analysis is recorded.

Pressing START/STOP again during the course of recording can stop recording.

Note: In the R-R mode, users can not set the speed. The constant speed is 25mm/s. That's because when recording in the R-R mode, the ECG wave is compressed to one fifth of the original wave length, and then 25mm/s is equal to 5mm/s.

5.8 Copy

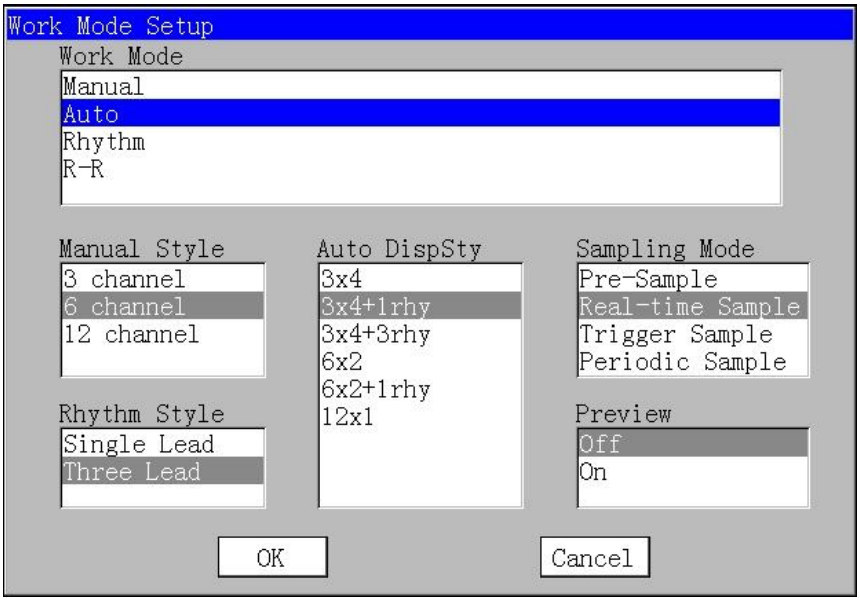
Pressing **COPY** key can recall the ECG data that was recorded last time. During the course of recording, pressing START/STOP again can stop recording.

Note: After return to the main interface from any other interfaces, the user should not immediately press START/STOP key to record in the AUTO mode or MANUAL mode within three seconds. Otherwise, the recorder will not respond.

5.9 Setup

5.9.1 Work Mode Setup

On the Work Mode Setup interface, users can set up Work Mode, Manual Style, Rhythm Style, Auto Display Style, Sampling Mode and Preview.



(1) Work Mode

Manual: In the Manual mode, users can determine which lead group needs to be recorded and set the parameters according to different lead group.

Auto: In the Auto mode, the lead groups are switched automatically according to different lead sequence while recording. When ECG signal of one lead group has been recorded within a certain time, it will be switched to another lead group automatically and begins to record the ECG signal of that lead group.

Rhythm: In the Rhythm mode, users can select rhythm leads to record 60s or 20s rhythm wave.

R-R: In the R-R mode, users can select a lead to record its R-R Histogram, R-R Trend Chart, 180s ECG waveform and all the R-R values.

(2) Manual Style

When Manual Style is set as 3 channel, users can record 3 leads ECG wave simultaneously.

When Manual Style is set as 6 channel, users can record 6 leads ECG wave simultaneously.

When Manual Style is set as 12 channel, users can record 12 leads ECG wave simultaneously.

(3) Auto Display Style

When Auto Display Style is set as **3×4**, 12 leads are displayed in 4 columns and 3 rows.

When Auto Display Style is set as **3×4+1rhy**, 12 leads are displayed in 4 columns and 3 rows, with one rhythm lead at the bottom.

When Auto Display Style is set as **3×4+3rhy**, 12 leads are displayed in 4 columns and 3 rows, with three rhythm leads at the bottom.

When Auto Display Style is set as **6×2**, 12 leads are displayed in 2 columns and 6 rows.

When Auto Display Style is set as **6×2+1rhy**, 12 leads are displayed in 2 columns and 6 rows, with one rhythm lead at the bottom.

When Auto Display Style is set as **12×1**, 12 leads are displayed in 12 channels.

(4) Rhythm Style

When Rhythm Style is set as Single Lead, in the Rhythm Work Mode, 60s ECG wave of the appointed single rhythm lead will be recorded.

When Rhythm Style is set as Three Lead, in the Rhythm Work Mode, 20s ECG wave of every appointed rhythm lead will be recorded.

(5) Sampling Mode

When Sampling Mode is set as **Pre-Sample**, 10s ECG data sampled before pressing START/STOP key will be recorded while recording.

When Sampling Mode is set as **Real-time Sample**, 10s ECG data sampled from the time of pressing START/STOP key will be recorded while recording.

When Sampling Mode is set as **Trigger Sample**, after pressing START/STOP key, if Arrhythmia ECG data, including Asystole, Ventricular Fibrillation/Ventricular Tachycardia, 5>PVCS>=3, Paired PVCS, Bigeminy, Trigeminy, R ON T, single PVC and Missed Beat, are detected during the course of sampling, recording will be triggered automatically.

When Sampling Mode is set as **Periodic Sample**, first users should set **Total Time** and **Interval** on the **Record Control Setup interface** of the **Record Info setup**. For example, if **Interval** is set to 2 minutes, the **Total Time** set to 24 minutes, by Pressing START/STOP key, it will record every 2 minutes and totally 12 times.

Note: No saving, copying or transmitting in the Period Sample Mode.

Note: Patient information will not be changed while carrying out the period recording.

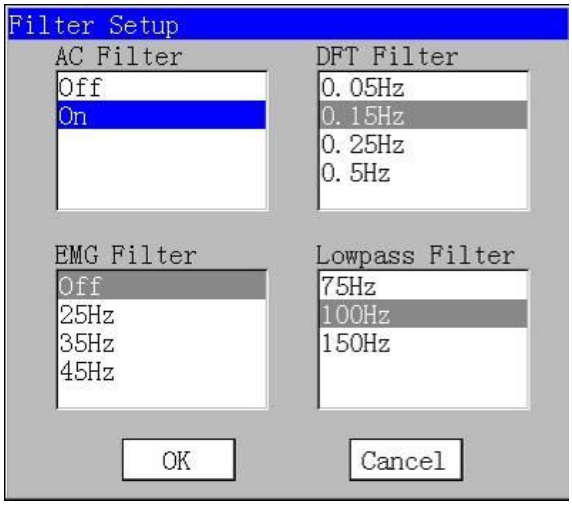
Note: Total Time must be greater than **Interval**, or else the setting will not be effective.

(6) Preview

When **Preview** is set as **on**, users can preview the ECG wave to be recorded.

When **Preview** is set as **off**, users can not preview the ECG wave to be recorded.

5.9.2 Filter Setup



(1) AC Filter

AC Filter suppresses AC interference without attenuating or distorting the ECG signal. Select **On** to turn on the function and select **Off** to turn off.

(2) DFT Filter

DFT Filter greatly reduces the baseline fluctuations without affecting the ECG signal. The purpose of this filter is to keep the ECG signals on the baseline of the printout. The setting value is the low limit of the frequency range, including **0.05Hz**, **0.15Hz**, **0.25Hz**, **0.5Hz**.

(3) EMG Filter

EMG Filter suppresses disturbances caused by strong muscle tremor. The cutoff frequency is defined at **25Hz**, **35Hz** or **45Hz**. Select **Off** to turn off the function.

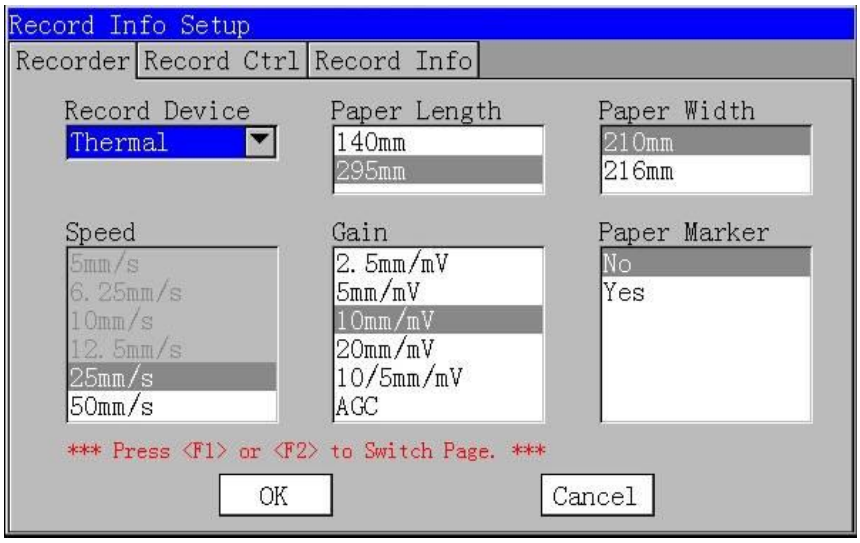
(4) Lowpass Filter

Lowpass Filter restricts the bandwidth of input signal. The cutoff frequency is defined at **150Hz**, **100Hz** or **75Hz**. All the input signals whose frequency is higher than the setting cutoff frequency will be attenuated.

5.9.3 Record Information Setup

There are three pages on the Record Info Setup interface: Recorder, Record Control and Record Info. Users can Press **F1** or **F2** function key to switch them.

5.9.3.1 Recorder Setup



(1) Recorder Device

Users can set the Recorder Device as Thermal, DeskJet or LaserJet.

The DeskJet and the LaserJet both belong to USB printer. When DeskJet or LaserJet is selected, the user should connect the USB printer recommended by EDAN to the **USB Socket 2** of electrocardiograph with specialized cable.

Note: please refer to **Chapter 5.15** to see the ECG Report printed by USB printer.

Note: USB printing works only in AUTO Pre-Sample mode, AUTO Real-time Sample mode, Copy, Freeze, Review and File Manage Window.

Note: Make sure that paper has been installed in USB printer before printing. Paper Empty may results in error.

Note: The USB printer can not be cancelled by **Start/Stop** key.

⚠**WARNING**⚠: It is forbidden to frequently insert and pull out U disk or USB printer.

(2) Paper Length

Users can set the length of one page of folded paper. 140mm or 295mm is available.

(3) Paper Width

Users can set the width of paper. 210mm or 216mm is available.

When the paper of 216mm width is used, the two movable parts in the Paper Tray and Casing of the recorder should be removed.

(4) Speed

Users can set the paper speed as 5, 6.25, 10, 12.5, 25 or 50mm/s. In the AUTO mode and Rhythm mode, only 25mm/s and 50mm/s are available. In the R-R mode, only 25mm/s is available.

(5) Gain

Users can set the indicated length of 1mV ECG on the paper.

Users can set Gain as 10mm/mV, 20mm/mV, 10/5mm/mV, AGC, 2.5mm/mV or 5mm/mV.

AGC means auto gain control. When ECG signal varies greatly, AGC can be selected to adjust the gain automatically according to actual signal.

10/5mm/mV means the gain of limb leads is set as 10mm/mV, while the gain of chest leads is set as 5mm/mV.

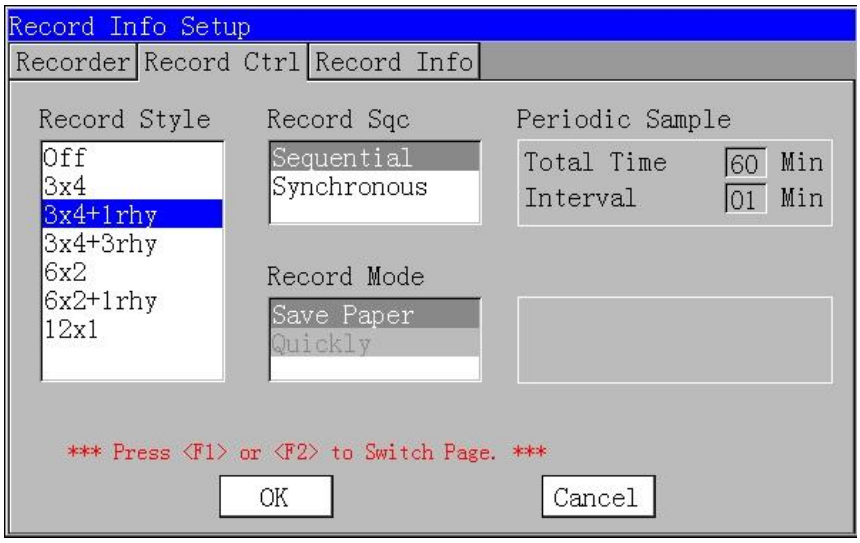
(6) Paper Marker

The **Paper Marker** is used to identify the start point of each page of the paper.

When the paper with black markers on the bottom is used and **Paper Marker** is set as **Yes**, the device can identify the start point of each page of the paper while recording.

When **Paper Marker** is set as **No**, the device can not identify the start point of each page of the paper while recording.

5.9.3.2 Record Control Setup



(1) Record Style

In the Auto Mode, when Record Style of Recorder Ctrl is set as**3x4, 3×4+1rhy, 3×4+3rhy, 6×2, 6×2+1rhy** or **12×1**, the ECG Report will be recorded.

In the Auto mode, when Record Style of Recorder Ctrl is set as **Off,** the ECG Report will not be recorded.

(2) Record Sequence

When **Record Sequence** is set as **Sequential**, the lead group is recorded one by one in a certain sequence.

When **Record Sequence** is set as **Synchronous**, ALL leads are recorded synchronously.

(3) Record Mode

When Record Mode is set as **Save Paper Mode,** pressing **START/STOP** key on the **Main Screen interface** to begin recording after the sampling time reaches 10s. The patient information and the ECG waves are recorded in the same paper.

When Record Mode is set as **Quickly Mode,** pressing **START/STOP** key on the **Main Screen interface** to begin recording, the patient information and the ECG waves are recorded in two papers.

Note: In the Auto Mode, **Quickly Mode** is available when **Sample Mode** is set as **Real-time Sample,**

Note: When **Record Style** is set as 3x4、3x4+1rhy or 3x4+3rhy, only Save Paper Mode is available. When **Record Style** is set as **12x1,** only **Quickly Mode** is available.

(4) Periodic Sample

The Interval and Total Time can set for Periodic Sample in the AUTO mode.

Note: please refer to **Chapter 5.9.1** to see the Periodic Sample in Work Mode Setup.

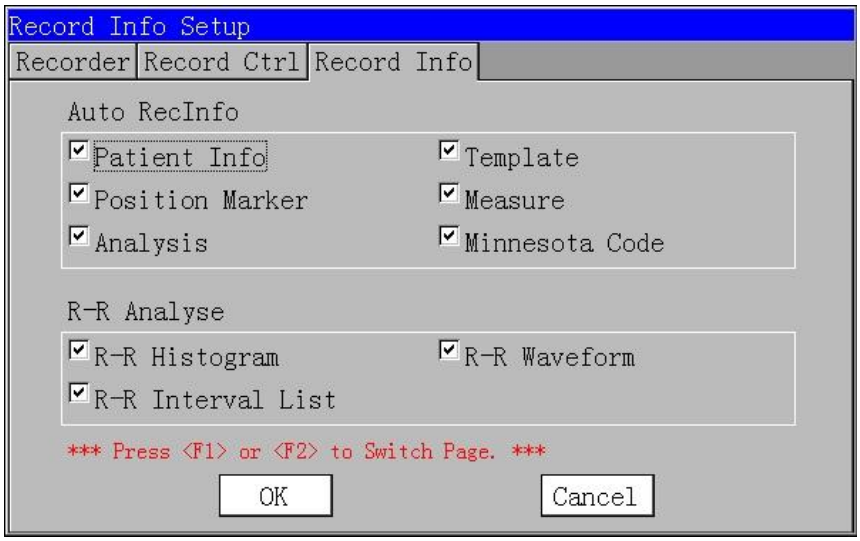
(5) 10-24s Sample

Users can set the time of sampling printing from 10 to 24 seconds, or disable this function.

When the Sample recording function is selected, in the Auto Mode, pressing START/STOP key on the Main **Screen** interface, the ECG waves are recorded according to the current setting.

Note: Users should select the function on the Advanced Setup interface.

5.9.3.3 Record Info Setup



(1) Auto Record Info

Auto Record Info includes Patient Info, Position Marker, Analysis, Template, Measure and Minnesota Code.

When **Patient Info, Position Marker, Analysis, Template, Measure** or **Minnesota Code** is selected, it will be recorded while recording.

When **Patient Info, Position Marker, Analysis, Template, Measure** or **Minnesota Code** is not selected, it will not be recorded while recording.

(2) R-R Analysis

R-R Analysis includes R-R Histogram, R-R Waveform and R-R Interval List.

When **R-R Histogram, R-R Waveform** or **R-R Interval List** is selected, it will be

recorded while recording.

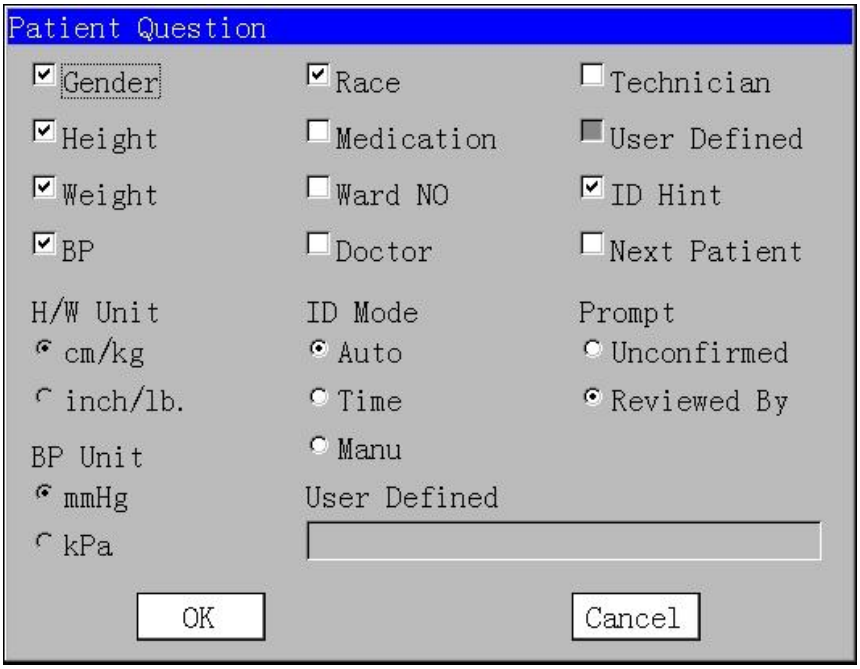
When **R-R Histogram, R-R Waveform or R-R Interval List** is not selected, it will not be recorded while recording.

Note: Users can press **Space** key to select or cancel on the Record Information Setup interface.

Note: The items on the Record Info Setup interface are valid only in the Auto mode, and Template and Position Marker do not work under the Auto Style of 3×4, 3×4+1rhy and 3×4+3rhy and the Style of 6x2 and 6x2+1rhy in the Quickly Mode.

Note: To get more information about the above contents, please refer to **Chapter 5.11 Auto Mode Record**.

5.9.4 Patient Question Setup



(1) Gender/Height/Weight/BP/Race/Medication/Ward NO/Doctor/Technician

When Gender, Height, Weight, BP, Race, Medication, Ward NO, Doctor or **Technician** is selected, the item will display on patient information interface.

When Gender, Height, Weight, BP, Race, Medication, Ward NO, Doctor or **Technician** is not selected**,** the item will not display on patient information interface.

(2) ID Hint

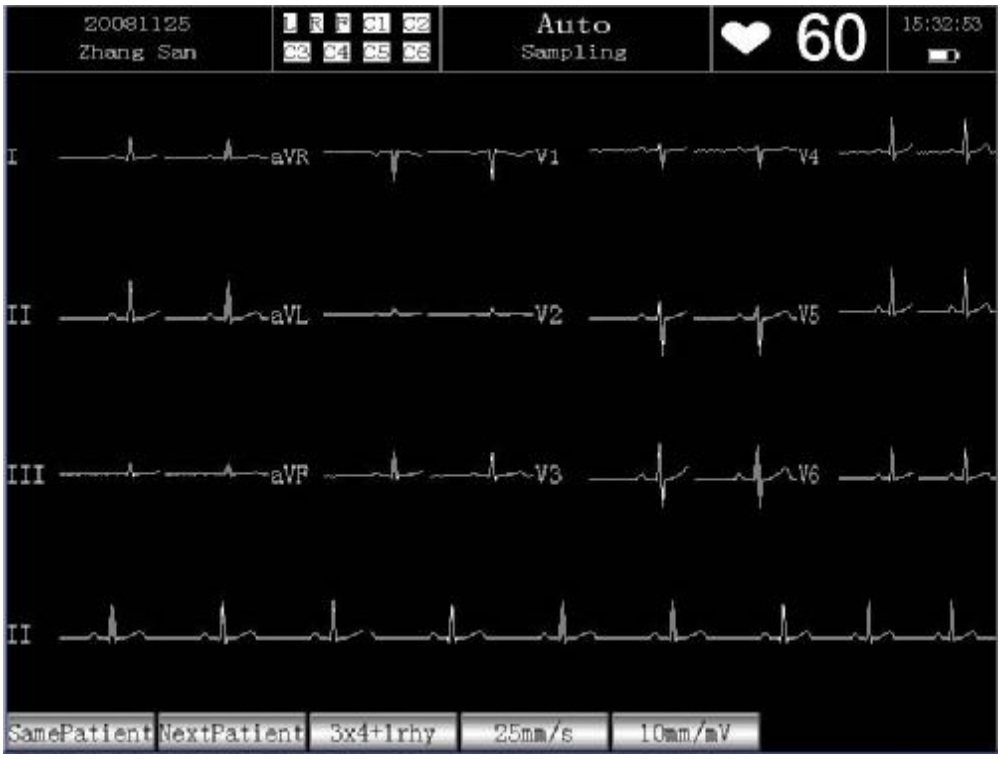
In the Auto mode and the rhythm mode, when **ID Generate Mode** is set as **manual**,

press the **START/STOP** key, if users have not input patient ID before operating, the Hint Information will pop up to remind users to input patient ID.

(3) Next Patient

In the Auto mode, when the Next Patient is selected, Press **START/STOP** key, the system will automatically turn into the **Next Patient interface** after a full ECG wave is recorded. On the **Next Patient interface**, pressing **Same Patient** function key can return to the Main Screen, all the patient information will keep the same; pressing **Next Patient** function key can return to the Main Screen, all the patient information will be cleared except for gender; pressing F3 function key can switch the Auto Record Style; pressing F4 function key can switch the paper speed, and pressing the F5 can switch the Gain.

On the **Next Patient** interface, users can print the current ECG Report again, according to the Auto Style, speed and Gain settings.



In the Auto mode**,** when **Next patient** is not selected, the system will not automatically turn into the **Next patient** interface.

(4) H/W Unit\BP Unit\User Defined

Not performed.

(5) ID Mode

Users can set the **ID Mode** as **Auto**, **time** or **manual**.

When ID **Generate Mode** is set as **Auto,** patient ID can be automatically generated. (Patient ID range: 0~1999, 999,999)

When ID **Generate Mode** is set as **time**, patient ID can be automatically generated according to the system time.

When ID **Generate Mode** is set as **manual**, patient ID can be manually inputted in patient information. (Only input ASCII code)

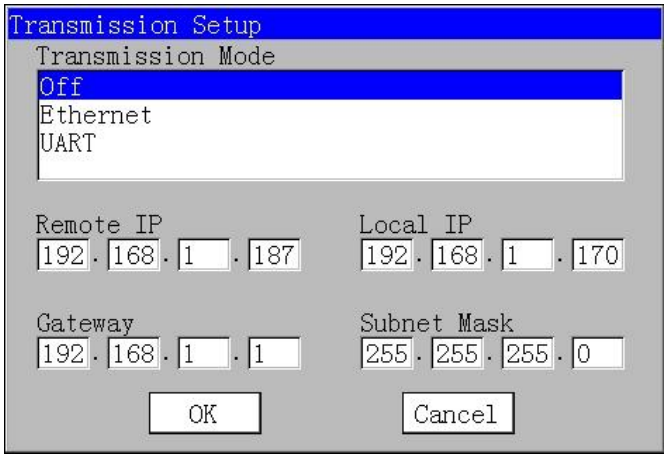
Note: When the patient ID is generated by system time, it can not be displayed on the Main Screen.

(6) Prompt

When **Prompt** is set as **Unconfirmed, Unconfirmed Report** is recorded in the ECG Report.

When **Prompt** is set as **Reviewed by, Report Reviewed by** is recorded in the ECG Report.

5.9.5 Transmission Setup



Note: To transfer ECG data to PC, SMARTECG-VIEWER software of EDAN must be installed in PC. Receive ECG Data window in the software should be opened up, and transfer type should be selected.

(1) Transmission Mode

When **Transmission Mode** is set as **off**, ECG data can not be transferred;

When **Transmission Mode** is set as **Ethernet**, firstly connect the net port of electrocardiograph and the net port of PC through an Ethernet cable recommended by the manufacturer. Secondly open the Receive ECG Data window of SMARTECG-VIEWER software in PC, select the transfer type "Net Trans" and press **Connect** button. Then set the Remote IP and Local IP in electrocardiograph. In the AUTO mode, ECG data can be transferred through net automatically after ECG recording is finished.

When **Transmission Mode** is set as **UART**, firstly connect the serial port 1 of electrocardiograph and the serial port of PC through a serial cable recommended by the manufacturer. Then open the Receive ECG Data window of SMARTECG-VIEWER software in PC, select the transfer type "Serial Trans", set the right PortNum and press **Connect** button. In the AUTO mode or the Rhythm mode, ECG data can be transferred through serial port automatically after ECG recording is finished.

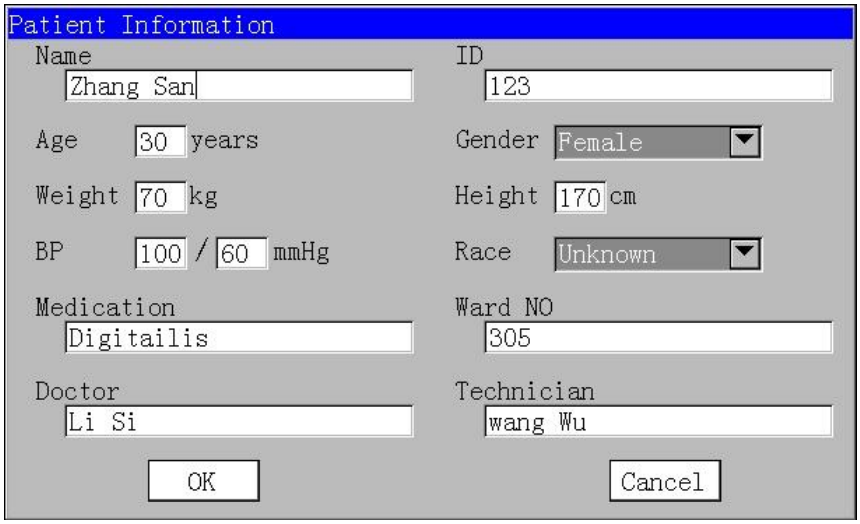
(2) Remote IP: Users can set Remote IP on Transmission Setup interface.

(3) Local IP: Users can set Local IP on Transmission Setup interface.

(4) Gateway: Users can set Gateway on Transmission Setup interface.

(5) Subnet Mask: Users can set Subnet Mask on Transmission Setup interface.

5.9.6 Patient Information



Note: The patient information can not be set or changed during the course of recording.

Name: Patient Name (SE-1200: Within 12 characters; SE-1200 Express: Within 20 characters)

ID: Patient ID (Within 10 characters; Range: 0~1999999999). For detail information, please refer to Chapter 5.9.4.

Age: Patient Age (Range: 1~255)

Gender: Patient Gender (Male/Female/Empty)

Weight (kg): Patient Weight (Range: 0~999)

Height (cm): Patient Height (Range: 0~999)

BP (mmHg): Patient Systolic Blood Pressure/Diastolic Blood Pressure

Race: Patient Race (unknown/ Oriental/ Caucasian/ Black/ Indian/ Mongolian/ Hispanic/ Asian/ Pacific/ other)

Medications: The medication which patient took previously (Within 20 characters)

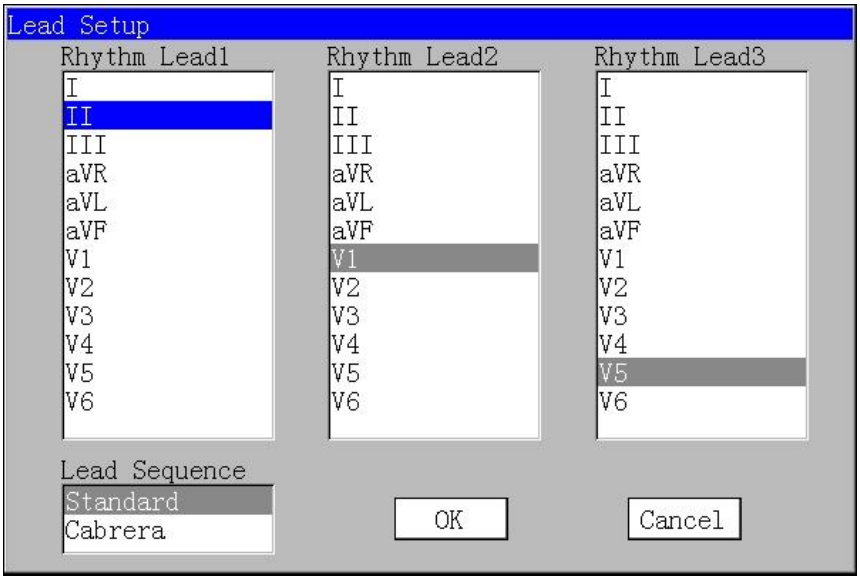
Ward No: Ward Number (Within 10 characters)

Medical: Medical Name (Within 20 characters)

Technician: Technician Name (Within 20 characters)

Note: Please refer to Chapter 5.2 for the method of inputting words on Patient Information interface.

5.9.7 Lead Setup



(1) Rhythm Lead 1/ Rhythm Lead 2/ Rhythm Lead 3

The rhythm lead can be one of 12 standard leads: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6.

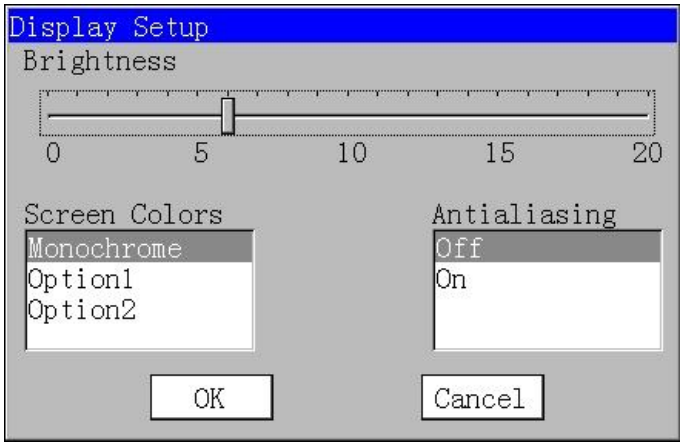
In the Auto mode, when Auto Style is set as 3×4+1rhy or 6×2+1rhy, the rhythm lead selected in Rhythm Lead 1 will be recorded while recording ECG; when Auto Style is set as 3×4+3rhy, 3 rhythm leads selected in Rhythm Lead 1 and Rhythm Lead 2 and Rhythm Lead 3 will be recorded while recording ECG.

In the Rhythm mode, when Rhythm Style is set as Single Lead, 60s waveform of the rhythm lead selected in Rhythm Lead 1 will be recorded while recording ECG; when Rhythm Style is set as Three Lead, 20s waveform of every rhythm lead selected in Rhythm Lead 1 and Rhythm Lead 2 and Rhythm Lead 3 will be recorded while recording ECG;

(2) Lead Sequence: Standard/Cabrera

Lead Sequence	**Lead group 1**	**Lead group 2**	**Lead group 3**	**Lead group 4**
Standard	I, II, III	aVR, aVL, aVF	V1, V2, V3	V4, V5, V6
Cabrera	aVL, I, -aVR	II, aVF, III	V1, V2, V3	V4, V5, V6

5.9.8 Display Setup



(1) Brightness

The brightness of LCD screen

Users can set the brightness within 0~20.

(2) Screen Colors (only for SE-1200 Express Screen)

The colors of LCD screen

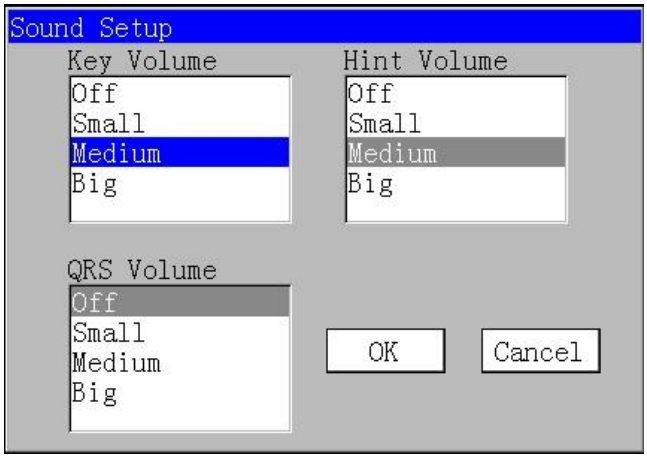
Users can set the screen colors as Monochrome, Option1 or Option 2.

(3) Antialiasing

When **Antialiasing** is set as **On**, system will automatically make waveform smooth.

When **Antialiasing** is set as **Off**, system will not make waveform smooth.

5.9.9 Sound Setup



(1) Key Volume

When users press keys on the keyboard, electrocardiograph gives a short beep sound, which is called Key Beep. Users can set the Key Volume as Small, Medium, Big or off. When set as off, there is no sound while pressing keys.

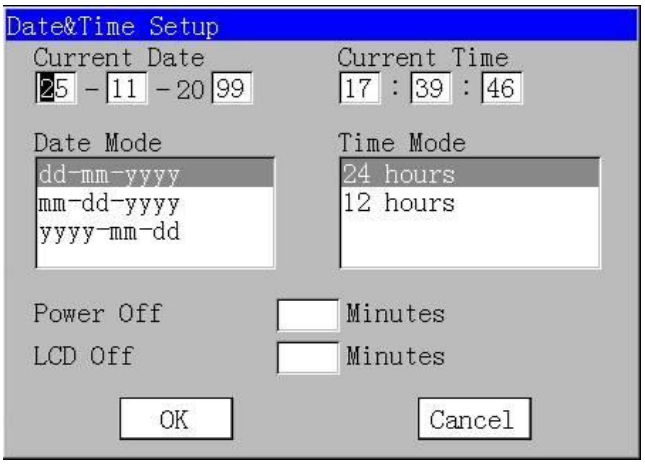
(2) QRS Volume

During the course of ECG displaying in main screen or ECG recording, electrocardiograph makes a short beep sound when an R wave has been detected. Users can set the QRS Volume as Small, Medium, Big or off. When set as off, there is no sound while detecting R wave.

(3) Hint Volume

Besides Key Beep and QRS Beep, electrocardiograph can make other hint sound. Users can set the Hint Volume as Small, Medium, Big or off. When set as off, there is no hint sound.

5.9.10 Date&Time Setup



(1) Current Date/Current Time

Users can set current date and current time on this interface, and it will be displayed on the paper while recording.

(2) Date Mode

Users can set Date Mode as dd-mm-yyyy, mm-dd-yyyy or yyyy-mm-dd.

(3) Time Mode

Users can set Time Mode as 24 hours or 12 hours.

Note: When finishing setting on this interface, users should click on OK to confirm and exit. The new setup will become effective when entering this interface again.

(4) Power Off

When the device is powered by the built-in rechargeable lithium battery, users can set the time of automatic power off.

When the Power Off is set as 000 Minutes, this function will not be effective.

Note: Power Off is counted from the time of last pressing the keys on the keyboard.

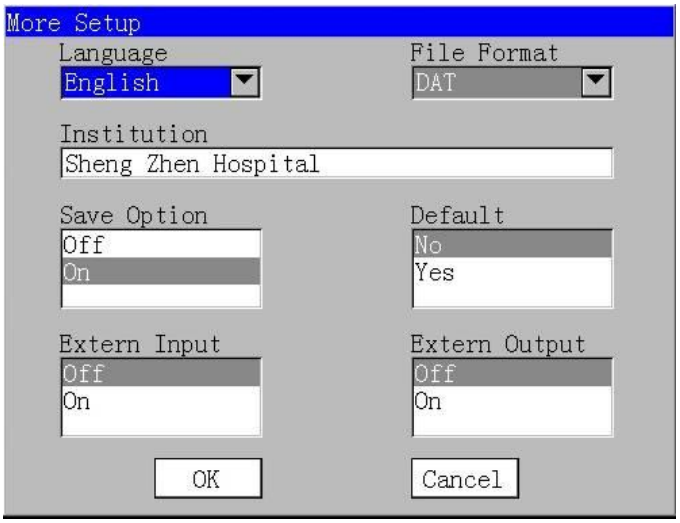
(5) LCD Off

Users can set the time of LCD off. When LCD is off, pressing any key on the keyboard can wake up LCD again.

When the LCD Off is set as 000 Minutes, this function will not be effective.

Note: LCD Off is counted from the time of last pressing the keys on the keyboard.

5.9.11 More Setup



(1) Language

Users can set language as any one contained in the software.

(2) Save Option

When Save Option is set as **On**, ECG data recorded in the Auto mode or Rhythm mode will be saved into the flash memory of the device automatically.

When Save Option is set as **Off**, ECG data recorded will not be saved into the flash memory of the device.

(3) Institution

Users can input institution name. (Within 20 characters)

(4) Extern Input/ Extern output

Extern input/output socket is equipped in electrocardiograph, through which electrocardiograph can receive signal from external equipment, or send signal to other external equipment. Set this item as **On** to turn on the function and **Off** to turn off.

Note: When **Extern Input** is set as **On**, the Touch Screen will become ineffective, and then the user should operate the device with keys on the keyboard.

(5) File Format

Not performed.

(6) Default

	Setup	Default
1	Work Mode	Auto
2	Sample Mode	Real-time Sample
3	Preview	Off
4	AC filter	On
5	EMG filter	Off
6	DFT filter	0.15Hz
7	Lowpass filter	100Hz
8	Gain	10mm/mV
9	Speed	25mm/s
10	Recorder style	6x2
11	Record Sequence	Sequential
12	Record Mode	Save Paper
13	Total Time(Periodic Sample)	60Min
14	Interval(Periodic Sample)	1 Min
15	10~24s adjusted printing	No
16	10~24s Sample Time	10s
17	Measure	On

18	Analysis	On
19	R-R Histogram	On
20	R-R Interval List	On
21	R-R Waveform	On
22	Gender\Height\Weight\BP\Race	On
23	Medication\Ward NO\Doctor\Technician	Off
24	ID Hint	On
25	Next Patient	Off
26	ID Mode	Auto
27	Prompt	Reviewed By
28	Transmission Mode	Off
29	Lead Sequence	Standard
30	Rhythm Lead 1	II
31	Rhythm Lead 2	V1
32	Rhythm Lead 3	V5
33	Screen Colors(Only for SE-1200 Express)	Option 1
34	Antialiasing	Off
35	QRS Volume	Off
36	Hint Volume	Medium
37	Key Volume	Medium
38	Save Option	On
39	Waveform Process	Off
40	Power Off	0
41	LCD Off	0
42	Search Type	Name

5.10 File

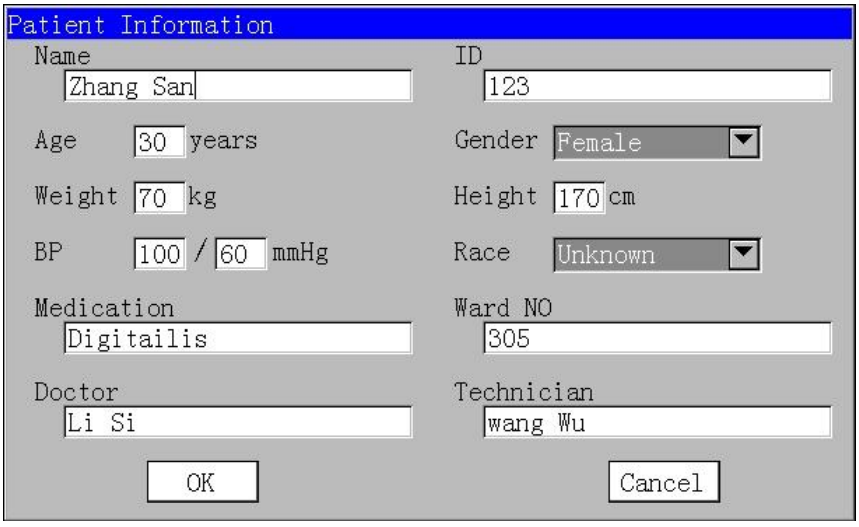
File Manage Window

Press **File** function key on the keyboard to enter the File Manage Window. In the File Manage Window, patient cases can be recorded, transmitted, displayed, searched or deleted. SE-1200 can accommodate 100 patient cases; SE-1200 Express can accommodate 200 patient cases.

If there is no patient case in the window, the following dialog box will be displayed when pressing function keys.

(1) Edit

Select a patient case and press **Edit** function key to pop up Patient Information window. Users can edit the information except patient ID and press **Ok** to confirm.



(2) Transmission

Before transmitting, users should enter the Transmission Setup interface to set the Transmission Mode as Ethernet/UART, connect Ethernet cable/UART cable, and set the SMARTECG-VIEWER software in PC.

Select a patient case and press **Trans** function key to begin transmitting.
If users do not set Transmission Mode before transmitting, dialog box (a) will pop up to remind users to select.
If users do not connect cable well or do not set the SMARTECG-VIEWER software well before transmitting, dialog box (b), (c) will pop up to remind users to connect or set again.

(a)

(b)

(c)

(d)

To transmit all cases in the File Manage Window, users can press **Trans All** function key to implement this operation. After all cases are transmitted, dialog box (d) will pop up.

If users do not set Transmission Mode or connect cable well or set the SMARTECG-VIEWER software well before transmitting, dialog box (a), (b), (c) will pop up to remind users to set or connect again.

⚠**WARNING**⚠: It is forbidden to insert or pull out U disk or USB printer in the course of transmitting.

(3) To USB/All to USB

Firstly, the user should insert the U disk recommended by EDAN to the USB Socket 2 of electrocardiograph.

Select a patient case and press **To USB** function key to copy this case into the ECGDATA folder of the U disk automatically. If U disk is not connected well, the information "U disk is not ready!" will be displayed on the LCD screen of electrocardiograph, then the user should connect the U disk again. If it fails to copy, the information "Copy file Error!" will pop up. After finishing coping successfully, the information "Copy file success!" will be displayed.

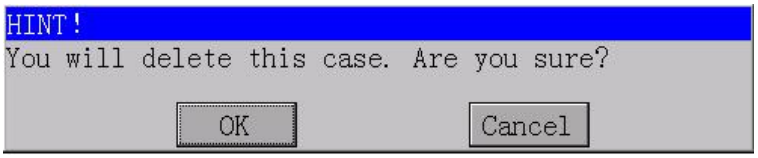
To copy all cases in the File Manage Window to U disk, the user can press **All to USB**

function key to carry out this operation. The hint information displayed during the course of **All to USB** is the same as the hint information displayed during the course of **To USB**.

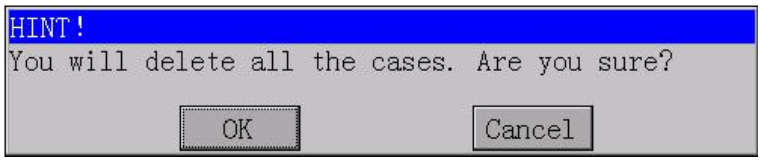
Note: Please use the U disk or insert the SD Card Reader that EDAN recommends. Only FAT format should be selected when formatting the U disk.

(4) Delete

Select a patient case and press **Delete** function key to pop up the following dialog box. Press **OK** to delete the selected case or press **Cancel** to cancel deleting.



To delete all cases in the File Manage Window, users can press **Del All** function key to pop up the following dialog box. Press **OK** to delete all cases or press **Cancel** to cancel deleting.



(5) Record

Select a patient case and press **Record** function key to begin recording.

During the course of recording, pressing START/STOP again can stop recording.

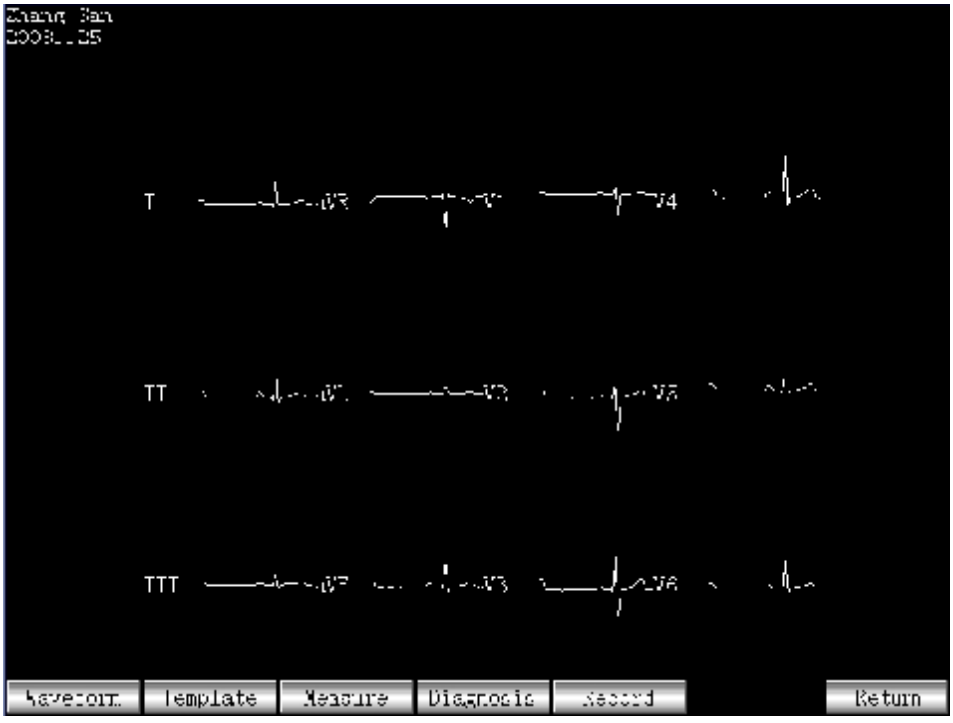
(6) Preview

Select a patient case and press **Preview** function key to enter the File Preview Window. The File Preview Window shows Patient Name, Patient ID, 12-channel ECG wave and five function keys (**Waveform**, **Template**, **Measure**, **Diagnosis, Record** and **Return**). In the File Preview Window, pressing **Record** function key can begin recording this case; pressing **Return** function key can return to the File Manage Window.

Note: Rhythm data can not be previewed.

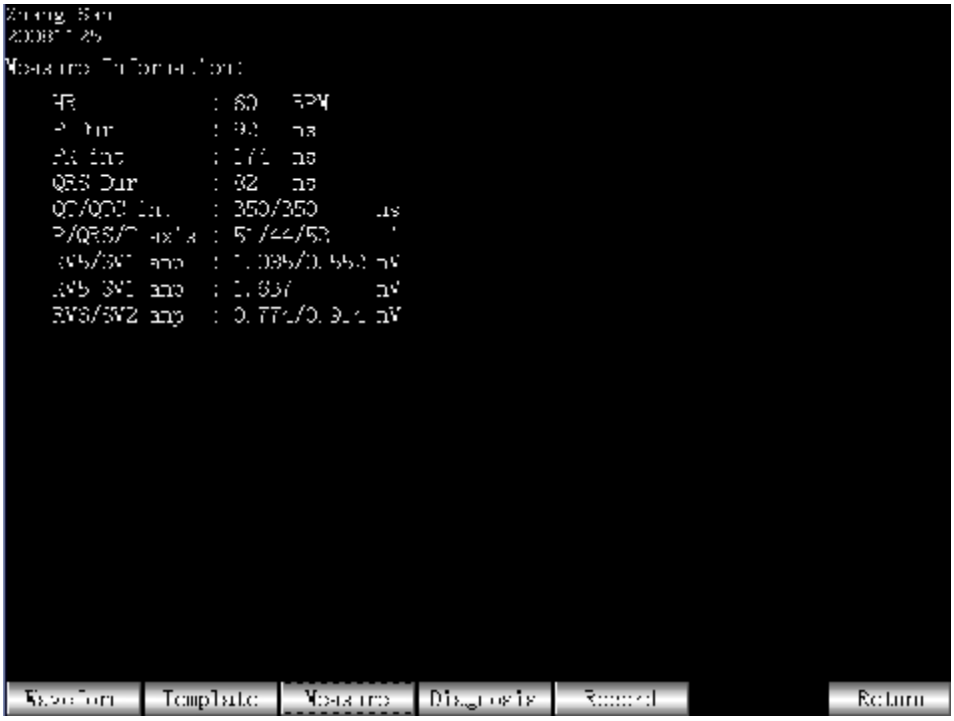
File Preview Window

If users need to view the average template of the selected case, press **Template** function key to enter the File Template Window, as the following figure shows.



File Template Window

If users need to view the Measure information of the selected case, press **Measure** function key to enter the File Measure Window, as the following figure shows.



File Measure Window

If users need to view the Diagnosis information of the selected case, press **Diagnosis** function key to enter the File Diagnosis Window, as the following figure shows.

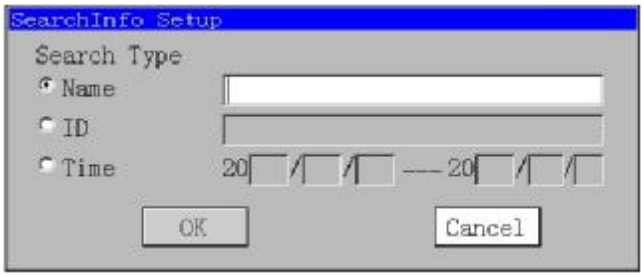
File Diagnosis Window

The File Measure Window shows Patient Name, Patient ID, Heart Rate, P Duration, PR interval, QRS Duration, QT/QTC interval, P/QRS/T axis, RV5/SV1 amplitude, RV5+SV1 amplitude, RV6/SV2 amplitude; The File Diagnosis Window shows Minnesota code and Diagnosis Information.

In the File Preview Window, pressing **Record** function key can begin recording this case; pressing **Return** function key can return to the File Manage Window.

7）Search

In the File Manager Window, pressing **Search** function key, the following Search Information Setup interface will pop up. On the Search Info Setup interface, selecting the **Name** or **ID**, the corresponding case will be found on the File Manage interface; selecting the **Time**, all corresponding cases from starting time to ending time will be found on the File Manage interface.



Note: Users can only select one of the Search Type on the Search Info Setup interface.
Note: The Time Mode is year, month and day on the Search Info Setup interface.

(8) Return

In the File Manage Window, pressing **Return** function key can return to the Main Screen.

Note: To save ECG data to the File Manage Window, please refer to **5.9.11 Save Option Settings**.

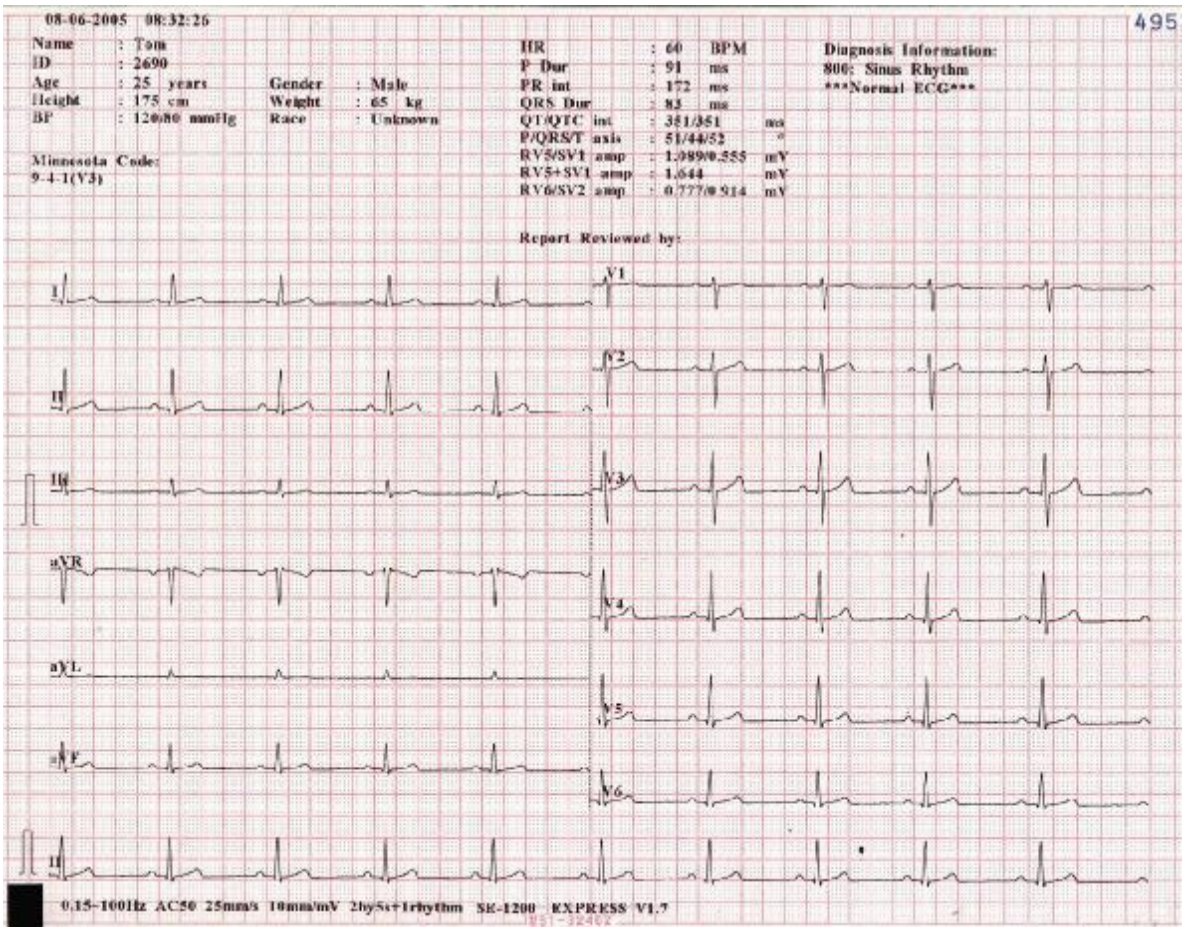
⚠**WARNING**⚠: Do not cut off the mains supply directly when no battery is installed in the device, or else, the stored data may be lost.

⚠**WARNING**⚠: When patient cases are being recorded, transmitted, deleted or copied, users can not turn off the electrocardiograph.

5.11 AUTO Mode Record

5.11.1 Example of 6×2+1rhy

5.11.1.1 Save Mode



The above figure shows the ECG record in the Auto Mode. The Auto Style is 6x2+1rhy. The ECG record includes:

Patient Information, Measure Information, Diagnosis Information, Minnesota Code, Report Reviewed By,

Current Date and Current Time

6×2+1rhy ECG wave

0.15~100Hz (0.15Hz DFT Filter, 100Hz Lowpass Filter) AC50 (50Hz AC Filter)

25mm/s (Paper Speed) 10mm/mV (Gain)

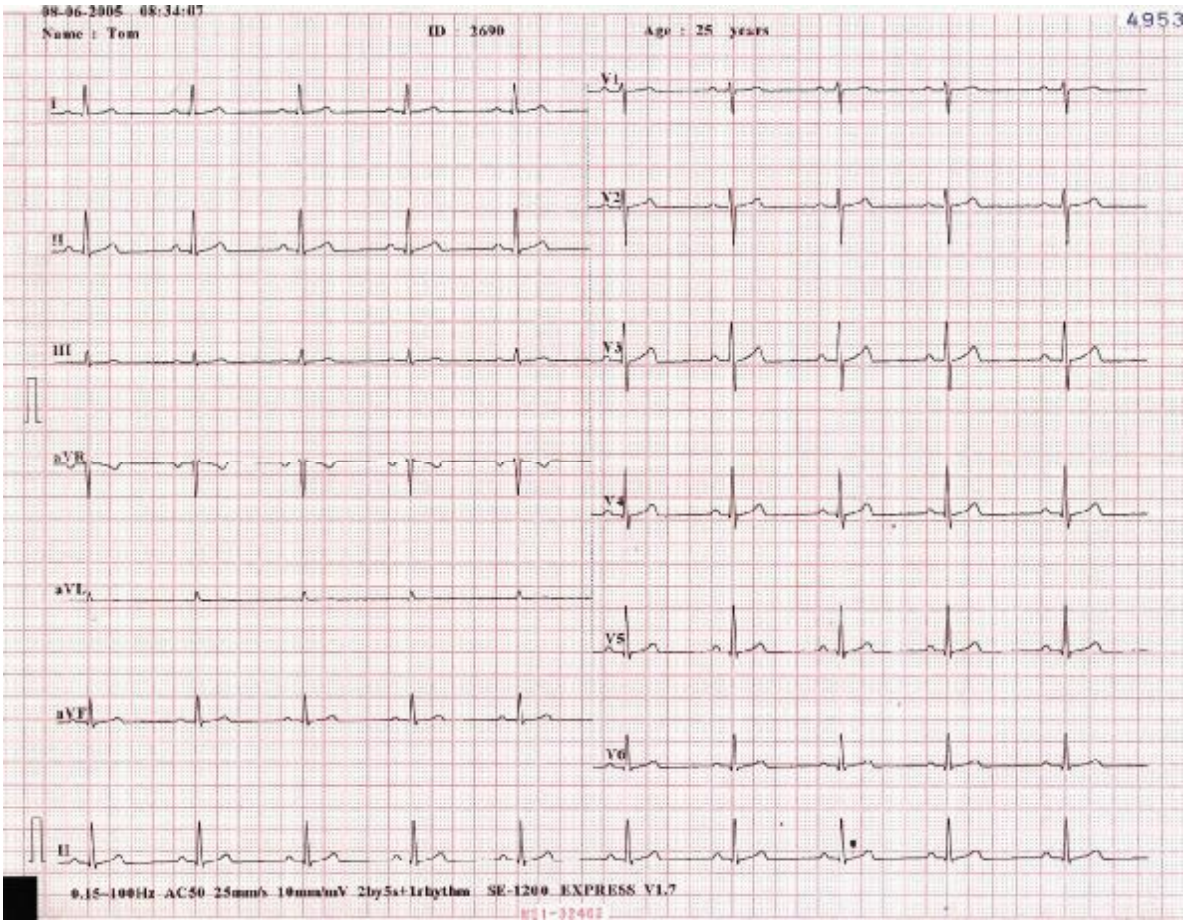
2 by 5s + 1 rhythm (12 leads are recorded in 2 groups of 6, and every group is recorded

about 5s, with one rhythm lead at the bottom simultaneously)

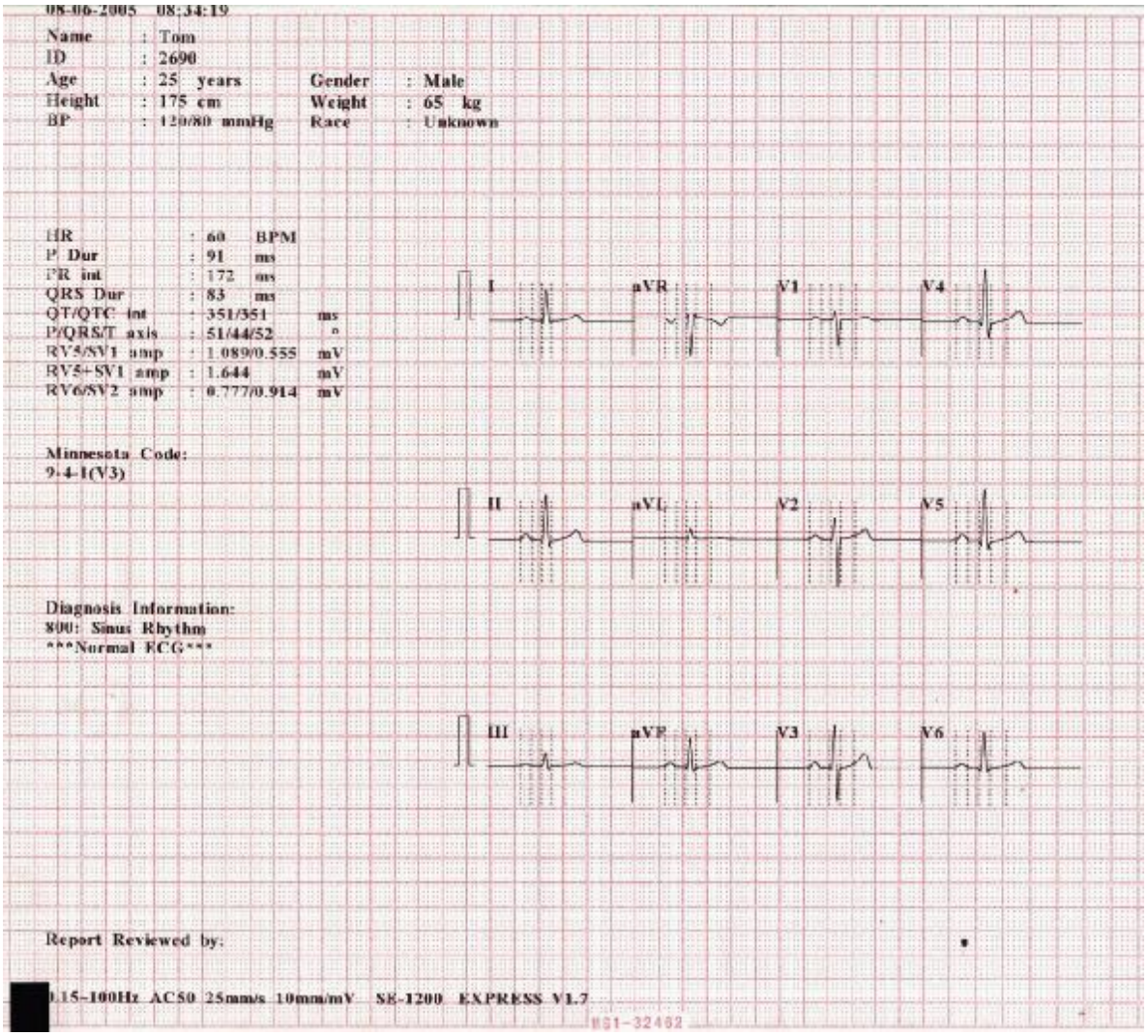
SE-1200 Express (Electrocardiograph Model)

V1.7 (Version number)

5.11.1.2 Quickly Mode



(a)


08-06-2005 08:34:19
Name : Tom
ID : 2690
Age : 25 years
Gender : Male
Height : 175 cm
Weight : 65 kg
BP : 120/80 mmHg
Race : Unknown
HR : 60 BPM
P Dur : 91 ms
PR int : 172 ms
QRS Dur : 83 ms
QT/QTC int : 351/351 ms
P/QRS/T axis : 51/44/52 °
RV5/SV1 amp : 1.089/0.555 mV
RV5+SV1 amp : 1.644 mV
RV6/SV2 amp : 0.777/0.914 mV
Minnesota Code:
9-4-1(V3)
Diagnosis Information:
800: Sinus Rhythm
Normal ECG
I
aVR
V1
V4
II
aVL
V2
V5
III
aVF
V3
V6
Report Reviewed by:
0.15-100Hz AC50 25mm/s 10mm/mV SE-1200 EXPRESS V1.7

(b)

The above figure (a) and (b) show the ECG record in the Auto Mode. The Template is set as on, and Auto Style is 6×2+1rhy.

Figure (a) shows:

ID: 2690 (Patient ID)

08-06-2005 08:34:07 (Current Date & Current Time)

⎍ (1mV calibration mark)

I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 (12 standard Leads) and ECG wave

II on the bottom (Rhythm Lead) and rhythm wave

0.15~100Hz (0.15Hz DFT Filter, 100Hz Lowpass Filter)

AC50 (50Hz AC Filter)

25mm/s (Paper Speed）

10mm/mV (Gain)

2 by 5s + 1 rhythm (12 leads are recorded in 2 groups of 6, and every group is recorded about 5s, with one rhythm lead at the bottom simultaneously)

SE-1200 Express (Electrocardiograph Model)

V1.7 (Version number）

Note: The version number recorded on the paper is just an example. The real version number can be found on the screen of electrocardiograph when you turn on the device.

Figure (b) shows: Patient Information, Measure Information, Minnesota Code, Diagnosis Information, Average Template, Technician, Report Confirmed By, Current Date and Current Time, 0.15Hz (DFT Filter), 100Hz (Lowpass Filter), AC50 (50Hz AC Filter), 25mm/s (Paper Speed), 10mm/mV (Gain), SE-1200 Express(Electrocardiograph Model), V1.7 (Version number).

Patient Information includes:

ID, Name, Age, Gender, Height, Weight, BP, Race, Ward No

Measure Information includes:

HR(Heart Rate)

P Dur----P wave duration: mean of duration of P-wave from several of 12 selected dominant beats;

PR int----P-R interval: mean of P-R interval from several of 12 selected dominant beats;

QRS Dur----QRS complex duration: mean of duration of QRS complexes from several of 12 selected dominant beats;

QT/QTC int----Q-T interval: mean of Q-T interval from several of 12 selected dominant beats/Normalized QT interval;

P/QRS/T axis----dominant direction of the average integrated ECG vectors;

RV5/SV1 amP----The maximum of amplitude of R or R' wave of one selected dominant beat from lead V5/ The maximum of amplitude of S or S' wave of one selected dominant beat from lead V1;

RV5+SV1 amP---- Sum of RV5 and SV1;

RV6/SV2 amP---- The maximum of amplitude of R or R' wave of one selected dominant beat from lead V6/ The maximum of amplitude of S or S' wave of one selected dominant beat from lead V2;

Diagnosis Information:

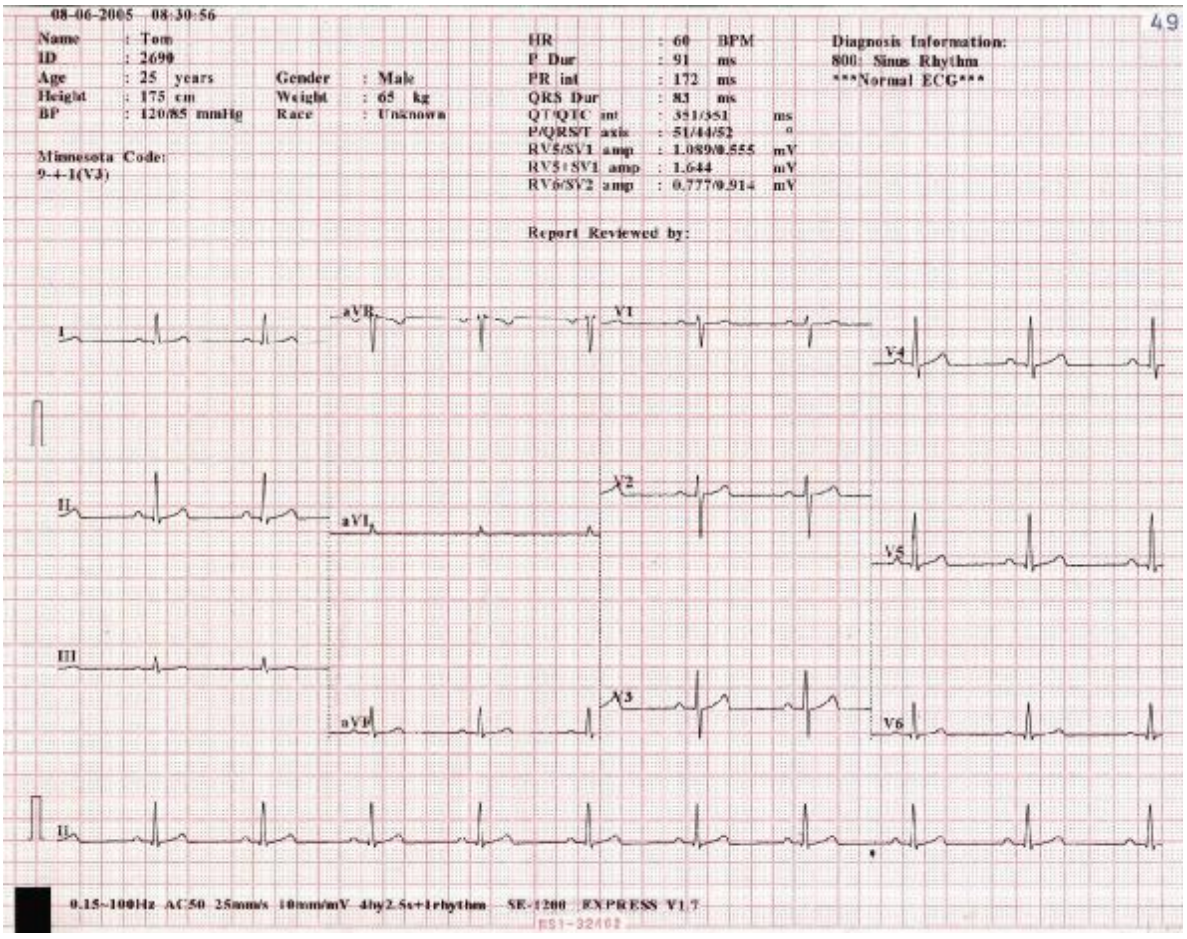
Diagnosis Information shows the auto diagnosis result.

Average Template:

Average Template shows the average value of 10s sampled ECG signal of every lead.

The dashed on the template is Position Marker. It respectively marks the start points and end points of P-wave and QRS-wave, and the end point of T-wave.

5.11.2 Example of 3×4+1rhy



The above figure shows the ECG record in the Auto Mode. The Auto Style is 3×4+1rhy. The ECG record includes:

Patient Information, Measure Information, Diagnosis Information, Minnesota Code, Report Reviewed By,

08-06-2005 08:30:56 (Current Date and Current Time)

3×4+1rhy ECG wave

0.15~100Hz (0.15Hz DFT Filter, 100Hz Lowpass Filter) AC50 (50Hz AC Filter)

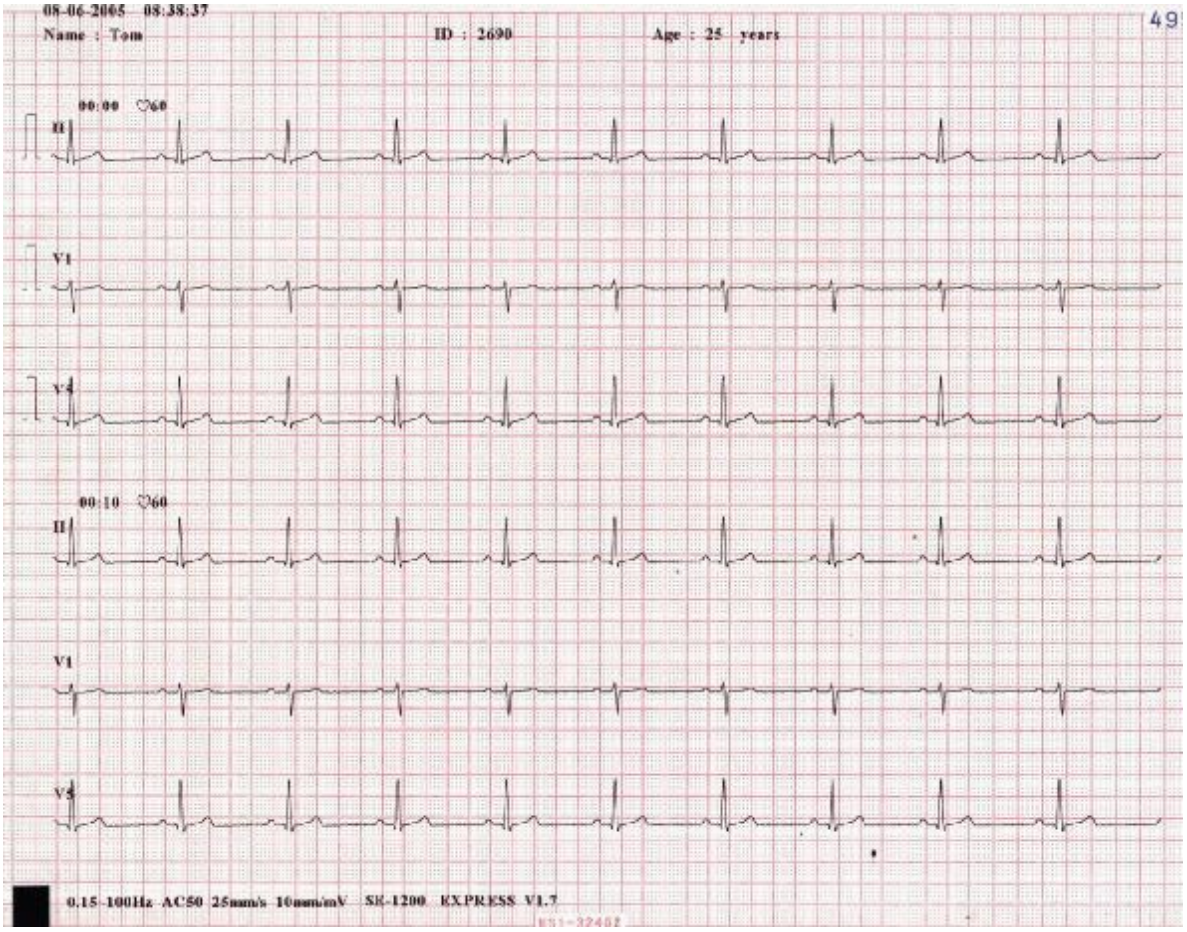
25mm/s (Paper Speed) 10mm/mV (Gain)

4 by 2.5s + 1 rhythm (12 leads are recorded in 4 groups of 3, and every group is recorded about 2.5s, with one rhythm lead at the bottom simultaneously)

SE-1200 Express (Electrocardiograph Model) V1.7 (Version number)

Note: Please refer to Chapter 5.11.1 for the explanation of Patient Information, Measure Information and Diagnosis Information.

5.12 RHYTHM Mode Record



The figure above shows the ECG record in the Rhythm Mode, and the Rhythm Style is Three Lead.

ID: 2690(Patient ID)

08-06-2005 08:38:37 (Current Date & Current Time)

00:00, 00:10 (Timer)

60 (Heart Rate)

⎍ (1mV calibration mark) II, V1, V5 (Rhythm Lead name）

20 seconds rhythm waveform of lead II/ V1/ V5

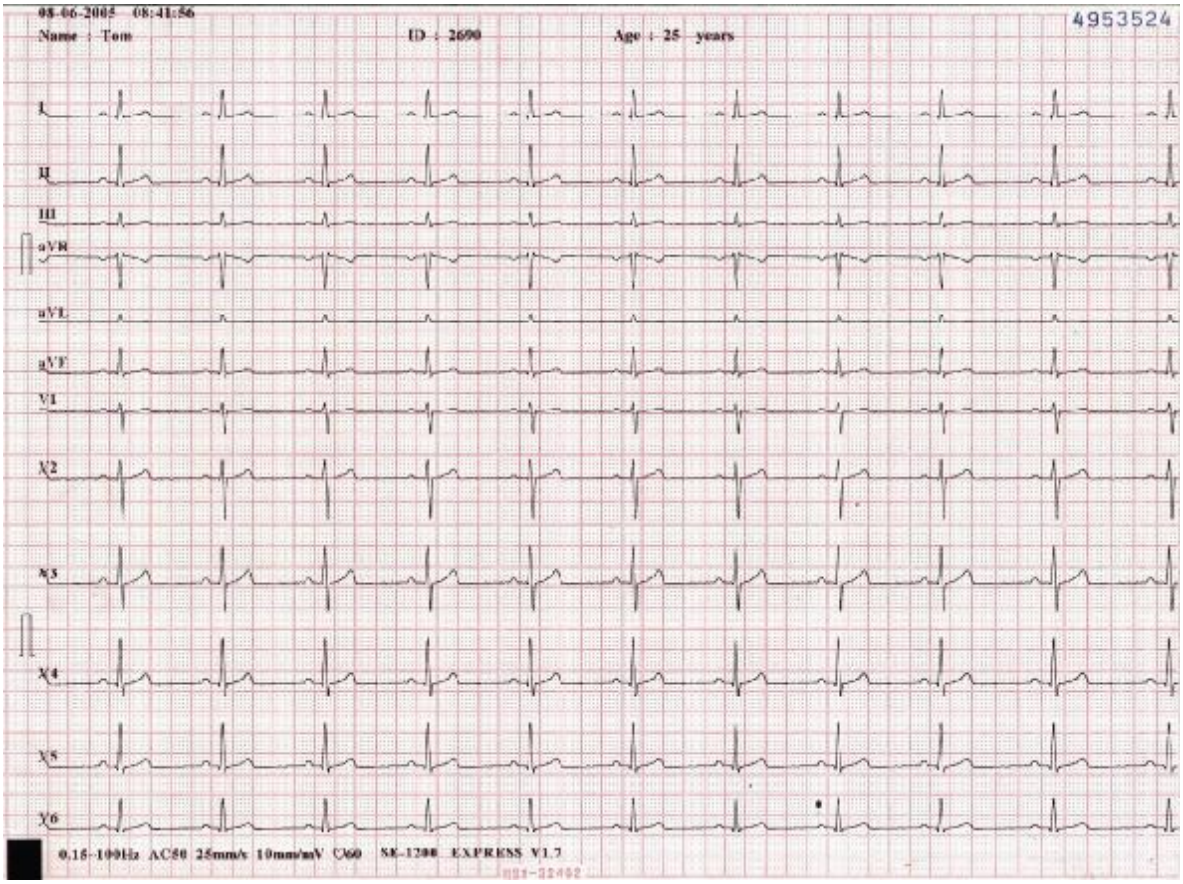
0.15~100Hz (0.15Hz DFT Filter, 100Hz Lowpass Filter)

AC50 (50Hz AC Filter) 25mm/s (Paper Speed）

10mm/mV (Gain) SE-1200 Express (Electrocardiograph Model)

V1.7 (Version number）

5.13 MANUAL Mode Record



The figure above shows the ECG record in the Manual Mode, and the Manual Style is 12- channel.

ID: 2690 (Patient ID)

08-06-2005 08:41:56 (Current Date & Current Time)

⎍ (1mV calibration mark)

I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 (12 standard Leads）

ECG waveform of 12 standard leads

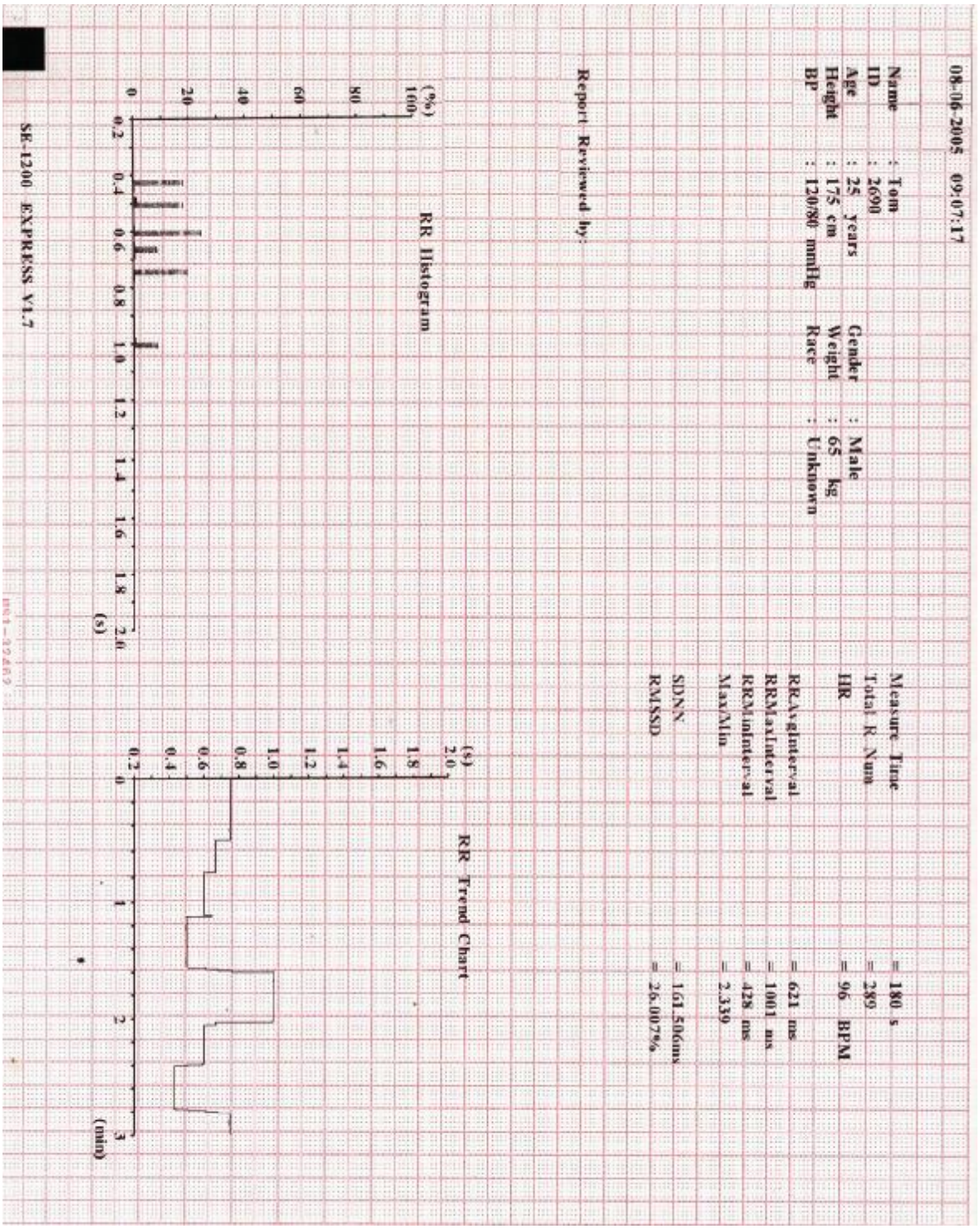
0.15~100Hz (0.15Hz DFT Filter, 100Hz Lowpass Filter)

AC50 (50Hz AC Filter)　　25mm/s (Paper Speed）

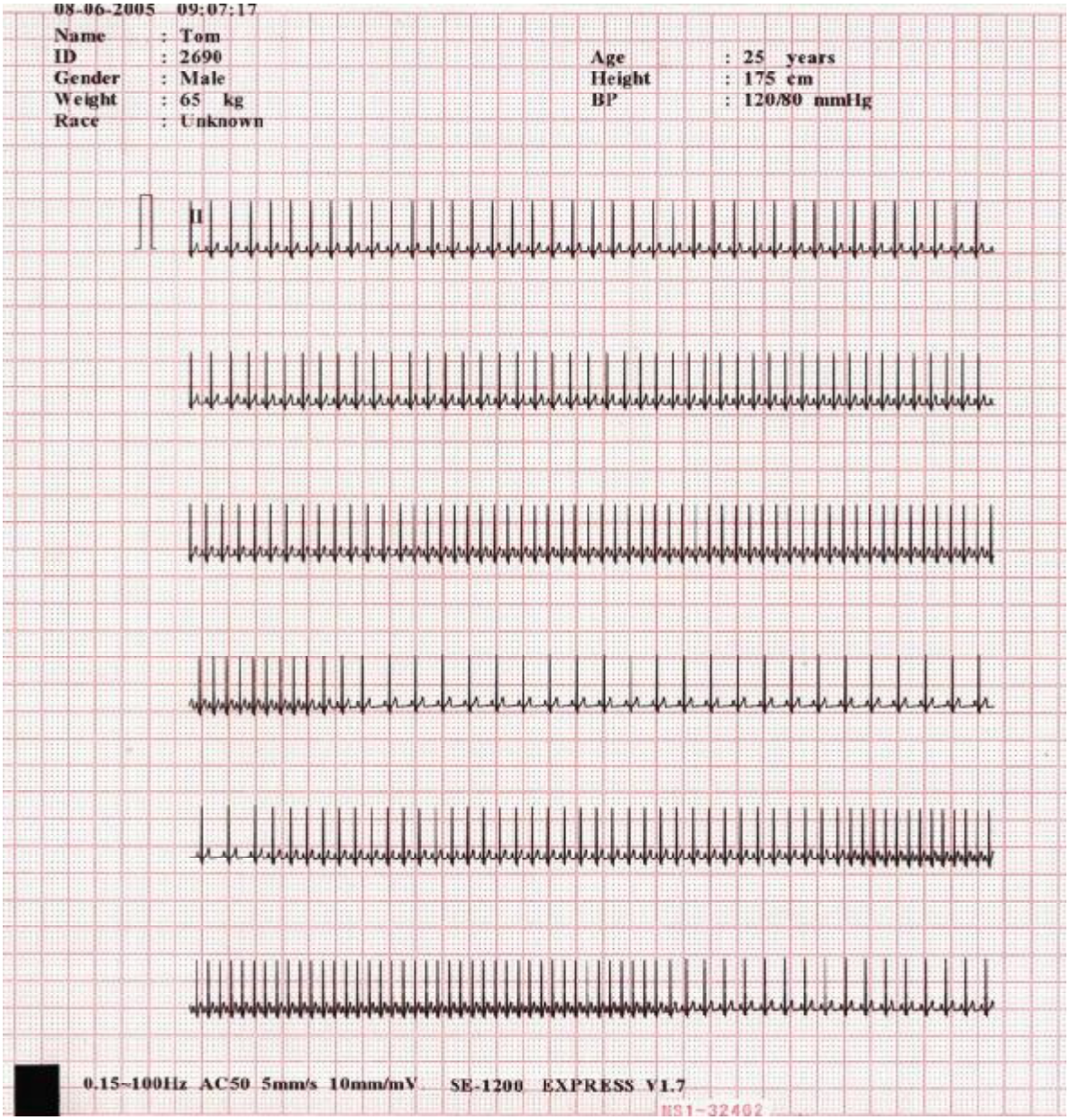
10mm/mV (Gain)　　♡60（Heart Rate）

SE-1200 Express (Electrocardiograph Model)　　V1.7 (Version number）

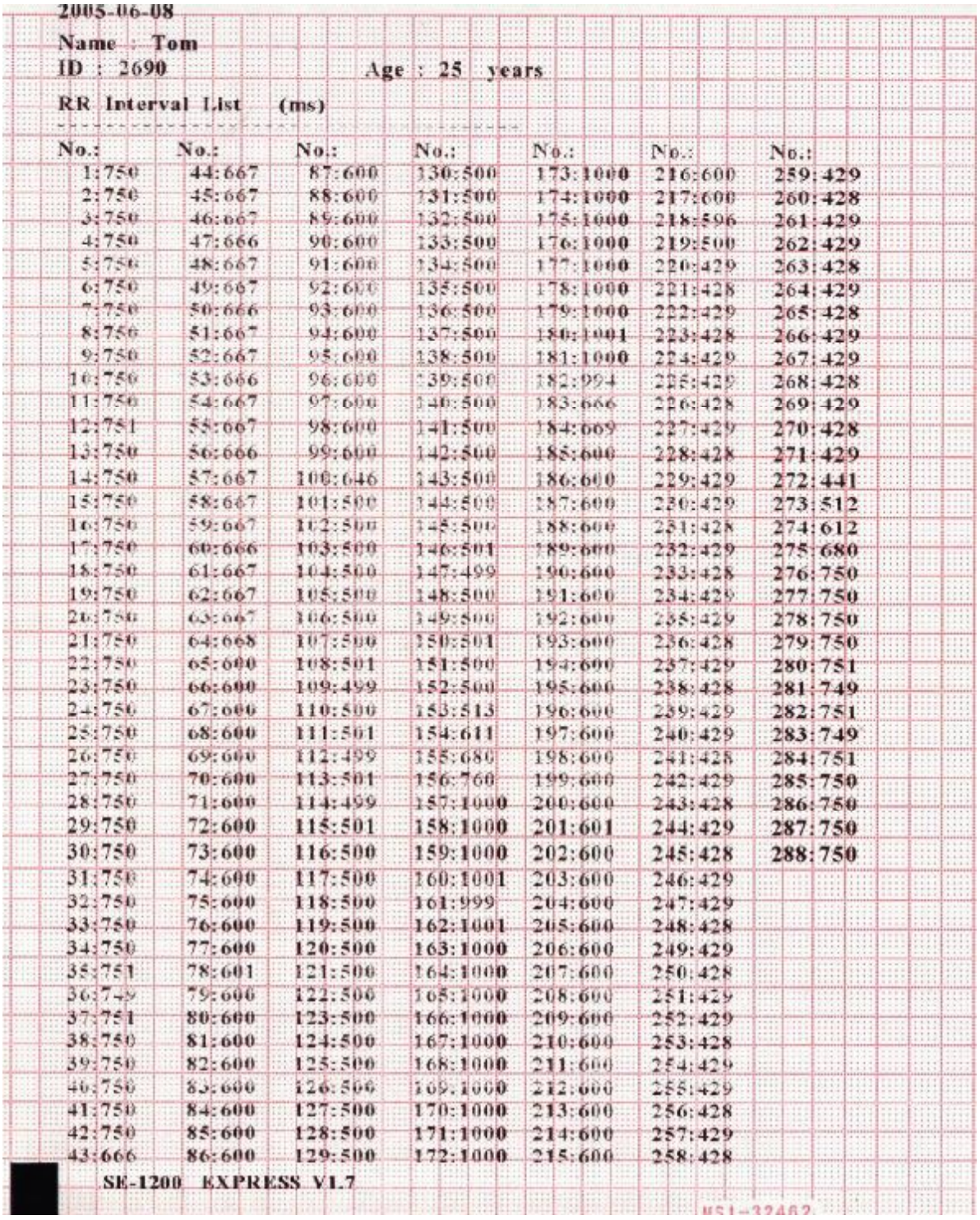
5.14 R-R Mode Record



(a)


08-06-2005 09:07:17
Name : Tom
ID : 2690
Gender : Male
Weight : 65 kg
Race : Unknown
Age : 25 years
Height : 175 cm
BP : 120/80 mmHg
II
0.15~100Hz AC50 5mm/s 10mm/mV SE-1200 EXPRESS V1.7

(b)



2005-06-08

Name : Tom

ID : 2690 Age : 25 years

RR Interval List (ms)

No.:	No.:	No.:	No.:	No.:	No.:	No.:
1:750	44:667	87:600	130:500	173:1000	216:600	259:429
2:750	45:667	88:600	131:500	174:1000	217:600	260:428
3:750	46:667	89:600	132:500	175:1000	218:596	261:429
4:750	47:666	90:600	133:500	176:1000	219:500	262:429
5:750	48:667	91:600	134:500	177:1000	220:429	263:428
6:750	49:667	92:600	135:500	178:1000	221:428	264:429
7:750	50:666	93:600	136:500	179:1000	222:429	265:428
8:750	51:667	94:600	137:500	180:1001	223:428	266:429
9:750	52:667	95:600	138:500	181:1000	224:429	267:429
10:750	53:666	96:600	139:500	182:994	225:429	268:428
11:750	54:667	97:600	140:500	183:666	226:428	269:429
12:751	55:667	98:600	141:500	184:669	227:429	270:428
13:750	56:666	99:600	142:500	185:600	228:428	271:429
14:750	57:667	100:646	143:500	186:600	229:429	272:441
15:750	58:667	101:500	144:500	187:600	230:429	273:512
16:750	59:667	102:500	145:500	188:600	231:428	274:612
17:750	60:666	103:500	146:501	189:600	232:429	275:680
18:750	61:667	104:500	147:499	190:600	233:428	276:750
19:750	62:667	105:500	148:500	191:600	234:429	277:750
20:750	63:667	106:500	149:500	192:600	235:429	278:750
21:750	64:668	107:500	150:501	193:600	236:428	279:750
22:750	65:600	108:501	151:500	194:600	237:429	280:751
23:750	66:600	109:499	152:500	195:600	238:428	281:749
24:750	67:600	110:500	153:513	196:600	239:429	282:751
25:750	68:600	111:501	154:611	197:600	240:429	283:749
26:750	69:600	112:499	155:680	198:600	241:428	284:751
27:750	70:600	113:501	156:760	199:600	242:429	285:750
28:750	71:600	114:499	157:1000	200:600	243:428	286:750
29:750	72:600	115:501	158:1000	201:601	244:429	287:750
30:750	73:600	116:500	159:1000	202:600	245:428	288:750
31:750	74:600	117:500	160:1001	203:600	246:429	
32:750	75:600	118:500	161:999	204:600	247:429	
33:750	76:600	119:500	162:1001	205:600	248:428	
34:750	77:600	120:500	163:1000	206:600	249:429	
35:751	78:601	121:500	164:1000	207:600	250:428	
36:749	79:600	122:500	165:1000	208:600	251:429	
37:751	80:600	123:500	166:1000	209:600	252:429	
38:750	81:600	124:500	167:1000	210:600	253:428	
39:750	82:600	125:500	168:1000	211:600	254:429	
40:750	83:600	126:500	169:1000	212:600	255:429	
41:750	84:600	127:500	170:1000	213:600	256:428	
42:750	85:600	128:500	171:1000	214:600	257:429	
43:666	86:600	129:500	172:1000	215:600	258:428	

SE-1200 EXPRESS V1.7

(c)

The above figure (a), (b) and (c) show the ECG record in the R-R Mode.

Figure (a) shows:

Current Date & Current Time

Patient Information (Name, ID, Gender, Age, Height, Weight, BP)

Measure Time

Total R Num (Total R-wave number)

HR (Heart Rate)

RR Avg Interval (Average RR interval)

RR Max Interval (Maximum RR interval)

RR Min Interval (Minimum RR interval)

Max/Min (Ratio of Maximum RR interval to Minimum RR interval)

SDNN (Standard Deviation of Normal to Normal Intervals)

RMSSD (The Root Mean Square Successive Difference)

RR Histogram

RR Trend Chart

Figure (b) shows:

Current Date & Current Time

Patient Information (Name, ID, Gender, Age, Height, Weight, BP)

Gain, Speed, Filter

(1mV calibration mark)

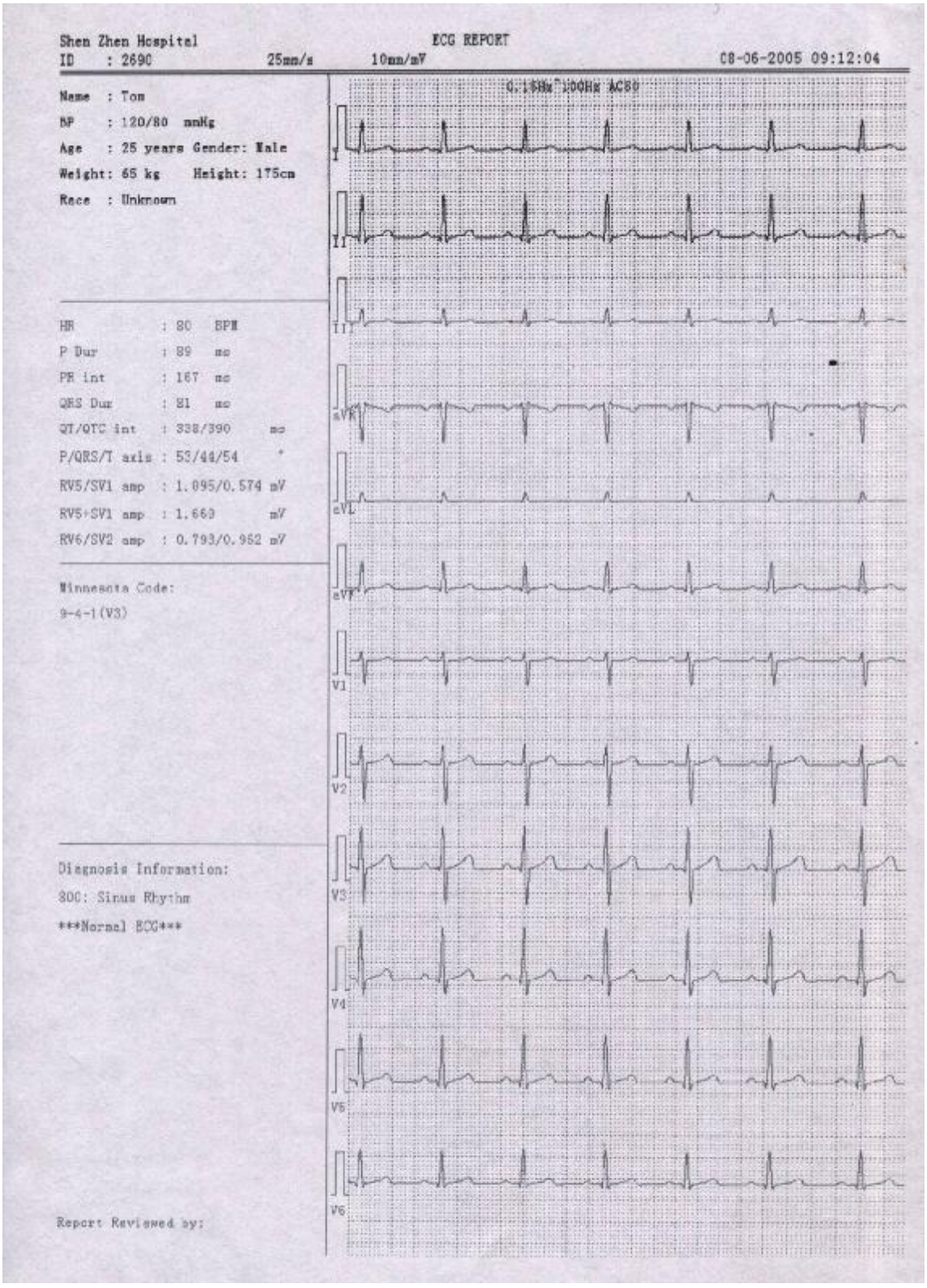
II (Lead name)

180s ECG wave of Lead II

Figure (c) shows:

All the RR values within the measure time

5.15 ECG Report



As figure above shows, ECG Report printed by USB printer includes:

ID, Paper speed, Gain, Date and time;

Name, BP, Age, Gender, Weight, Height, Race, Medications, Ward No, Technician;

Heart Rate, P duration, PR interval, QRS duration, QT/QTC interval, P/QRS/T axis, RV5/SV1 amplitude, RV5+SV1 amplitude, RV6/SV2 amplitude;

Minnesota code;

Diagnosis information;

Report Confirmed by;

DFT Filter, Lowpass Filter, AC Filter;

ECG waveform of 12 leads

5.16 Switch Off

When built-in battery used, after finishing ECG record, press **Power ON/OFF** key to display the information "System is shutting down…" on the screen. After a few seconds, the device will be off.

When mains supply used, after finishing ECG record, press **Power ON/OFF** key to display the information "System is shutting down…" on the screen. After a few seconds, the device will be off. And then pull off the plug from the outlet.

Note: When switching off the device, please operate it according to the sequence above strictly, or else there will be something wrong on the screen.

Note: Do not keep on pressing the **Power ON/OFF** key when the device displays the hint information "System is shutting down…" on the screen.

6 Hint Information

Hint information and corresponding cause provided by electrocardiograph is listed in Table 6-1.

Table 6-1 Hint Information and Causes

Hint Information	Causes
Lead off	Electrodes fall off from patient or patient cables fall off from the unit.
Battery Weak	The built-in battery is weak.
No Paper	Recording paper is not loaded or it has run out.
Paper Error	Feed paper error.
doing	The system is being sampled periodically
Sampling/Analyzing/Recording	ECG signal is being sampled / analyzed/ recorded.
Learning	The self-study process of arrhythmia arithmetic in the Trigger Sample mode
Transmitting	ECG data is being transmitted from electrocardiograph to PC through Ethernet or serial port in the Auto mode
Transmit Fail	ECG data fails to be transmitted from electrocardiograph to PC through Ethernet or serial port in the Auto mode
Detecting	The examining process of arrhythmia data in the Trigger Sample mode
Memory Full	The amount of patient cases in the File Manage Window of SE-1200 exceeds 100 The amount of patient cases in the File Manage Window of SE-1200 Express exceeds 200
Modu Error	There is something wrong with the signal sample module.
Demo Display	The system is in demonstration mode.
Overload	The direct current offset voltage on an electrode is too high.
U Disk	A U disk is connected to the USB interface.
USB Printer	A USB printer is connected to the USB interface.

7 Technical Specifications

Safety Standards	IEC 60601-1: 1988+A1+A2, EN 60601-1:1990+A1+A2, IEC/EN60601-1-2: 2001+A1, IEC/EN60601-2-25, ANSI/AAMI EC-11		
Classification	Anti-electric-shock type:	Class I with internal power supply	
	Anti-electric-shock degree:	Type CF	
	Degree of protection against harmful ingress of water:	Ordinary equipment (Sealed equipment without liquid proof)	
	Disinfection/sterilization method:	Refer to the user manual for details	
	Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas	
	Working mode:	Continuous operation	
	EMC:	Group I, type A	
Dimensions	420mm×330mm×120mm		
Weight	5.0kg (without recording paper and battery)		
Display	320×240 dot single color LCD Screen 800×600 multicolor LCD Screen		
Environment		Transport and Storage	Working
	Temperature:	-20 ºC ~+55 ºC	+5 ºC ~+40 ºC
	Relative Humidity:	25%~93% non-condensing	25%~80% non-condensing
	Atmospheric Pressure:	700hPa ~1060hPa	860hPa ~1060hPa
Power Supply	Mains Supply:	Rated input voltage =100V~240V	
		Rated frequency = 50/60Hz	
		Rated input power = 70VA	

	Built-in Lithium Battery Pack:	Rated voltage = 14.8V
		SE-1200 Express: Rated capacity = 4000mAh/4400mAh SE-1200: Rated capacity = 2000mAh /2200mAh /2400mAh
		When the capacity of battery is full, SE-1200 can work normally for nearly 2 hours; about 200 ECG of **3**×4+1r can be recorded in the Auto Mode. SE-1200 Express can work normally for nearly 3.5 hours; about 400 ECG of **3**×4+1rhy can be recorded in the Auto Mode.
		Charge mode: Constant current/voltage
		Charge current (standard) = $0.2C_5A$ (320mA)
		Charge voltage (standard) = (16.8-0.1V)
		Cycle life ≥ 300 times
	Power Consumption:	70VA (max)
	Fuse:	AC100V-240V: T1A; Ø5×20
Recording	Recorder:	Thermal dot-matrix recorder
	Recording Paper:	Folded paper, Rolled paper
	Paper Width:	216mm, 210mm
	Effective Width:	200mm, 195mm
	Paper Speed:	5mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s（±3%）
	Accuracy of data:	±5% (x-axis), ±5%(y-axis)
HR Recognition	Technique:	Peak-peak detection
	HR Range:	30 BPM ~300 BPM
	Accuracy:	±1BPM
ECG Unit	Leads:	12 standard leads
	Acquisition Mode:	simultaneously 12 leads

	A/D Resolution:	24 bits
	Time Constant:	≥3.2s
	Frequency Response:	0.05Hz ~ 150Hz
	Gain:	2.5, 5, 10, 20, 10/5, AGC (mm/mV)
	Input Impedance:	50MΩ(10Hz)
	Input Circuit Current:	≤10nA
	Input Voltage Range	<±5 mVpp
	Calibration Voltage:	1mV±2%
	DC Offset Voltage:	±600mV
	Noise:	<12.5μVp-p
	Multichannel crosstalk	≤0.5mm
	Filter	AC Filter: On/Off
		DFT Filter: 0.05/0.15/0.25/0.5
		EMG Filter: 25Hz/35Hz/45Hz/OFF
		LOWPASS Filter:150Hz/100Hz/75Hz
	CMRR	≥115dB
	Sampling Frequency	1000Hz
Patient Leakage Current:		<10μA (220V~240V)
Patient Auxiliary Current:		<0.1μA (DC)
Dielectric Strength:		4000V rms
External Input/Output (Optional)	Input	≥100kΩ; Sensitivity 10mm/V±5%; Single ended
	Output	≤100Ω; Sensitivity 1V/mV±5%; Single ended

8 Cleaning, Care and Maintenance

8.1 Cleaning

CAUTION:

Turn off the power before cleaning and disinfection. Mains supply must be switch off if it is in use.

8.1.1 Cleaning the Main Unit and Patient Cable

The surfaces of the main unit and patient cable can be wiped with a clean soft cloth damped in soapy water or non-caustic neutral detergent. After that, remove detergent remainder with a clean dry cloth.

8.1.2 Clean the Electrodes

Remove the remainder gel from the electrodes with a clean soft cloth first. Take the suction bulb and the metal cup of chest electrodes apart, and take the clamp and the metal part of the limb electrodes apart. Clean them in warm water and be sure there is no remainder gel. Dry the electrodes with a clean dry cloth or air dry naturally.

8.1.3 Clean the Print Head

Dirty and soiled thermal print head will deteriorate the record definition. So it should be cleaned at least once a month regularly.

Open the recorder casing and remove the paper. Wipe the print head gently with a clean soft cloth damped in 75% alcohol. For stubborn stain, soak it with a little alcohol first and wipe it off with a clean soft cloth. After air dried, load the recording paper and shut the casing of the recorder.

CAUTION:

Prevent the detergent from seeping into the main unit while cleaning. Do not immerse the unit or patient cable into liquid under any circumstances.

CAUTION:

Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.

8.2 Disinfection

To avoid permanent damage to the equipment, disinfection can be performed only when it has been considered as necessary according to your hospital's regulations.

Before disinfection clean the equipment first. Then wipe the surfaces of the unit and patient cable with hospital standard disinfectant.

CAUTION:

Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.

8.3 Care and Maintenance

8.3.1 Recharge and Replacement of Battery

1) Capacity Identification

Current capacity of the rechargeable battery can be identified according to the battery symbol in the top right corner on LCD screen.

For SE-1200 Express:

: Full capacity

: Capacity is limited, and hint information "Battery Weak" will be displayed on LCD screen. Recharge should be taken into account.

: Battery is weak, and hint information "Battery Weak" will be displayed on LCD screen. The battery should be recharged immediately.

For SE-1200:

: Full capacity

: Capacity is limited, and hint information "Battery Weak" will be displayed

on LCD screen. Recharge should be taken into account.

: Battery is weak, and hint information "Battery Weak" will be displayed on LCD screen. The battery should be recharged immediately.

2) Recharge

12-channel electrocardiograph is equipped with recharge control circuit together with built-in rechargeable lithium battery. When connect with the mains supply, the battery will be recharged automatically. And then the battery recharge indicator lamp (⇥▭) and the mains supply indicator lamp (∿) will be lit at the same time. During the course of recharging, the symbol " or " will flash in the top right corner of LCD screen. When the capacity of battery is full, the symbol will stop flashing, and the battery recharge indicator lamp (⇥▭) will be black.

Because of the capacity consumption during storage and transport, the capacity of battery is not full while using at the first time. Battery recharge should be considered before first usage.

3) Replacement

When the useful life of battery is over, or foul smell and leakage has been found, please contact with manufacturer or local distributor for replacement of battery.

⚠**WARNING**⚠:

- Only qualified service engineer authorized by EDAN can open the battery compartment and replace the battery. And the battery of same model and specification provided by manufacturer must be used.
- Danger of explosion -- Do not reverse the anode and cathode when connecting the battery.
- When the battery's useful life is over, contact the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

8.3.2 Recording Paper

Note: Recording paper provided by manufacturer should be used. Other paper may shorten thermal print head's life. And the deteriorated print head

may lead to illegible ECG record and block the advance of paper etc.

Storage requirements:

- Recording paper should be stored in dry, dark and cool area, avoiding excessive temperature, humidity and sunshine.
- Do not put the paper under fluorescence for long time.
- Be sure that there is no polyvinyl chloride or other chemicals in the storage environment, which will lead to color change of the paper.
- Do not overlap the recording paper long time, or else the ECG record may trans-print each other.

8.3.3 Maintenance of Main Unit, Patient Cable & Electrodes

The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

a) Inspect the equipment and accessories for mechanical and functional damage.

b) Inspect the safety related labels for legibility.

c) Inspect the fuse to verify compliance with rated current and breaking characteristics.

d) Verify the device functions properly as described in the instructions for use.

e) Test the protection earth resistance according to IEC/EN 60601-1: Limit 0.1ohm.

f) Test the earth leakage current according to IEC/EN 60601-1: Limit: NC 500uA, SFC 1000uA.

g) Test the patient leakage current according to IEC/EN 60601-1: Limit: 10uA (CF).

h) Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC/EN 60601-1: Limit: 50uA (CF).

The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

⚠**WARNING**⚠: Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure

and possible health hazards.

1) Main Unit

- Avoid excessive temperature, sunshine, humidity and dirt.
- Put on the dustproof coat after use and prevent from shaking violently when moving it to another place.
- Prevent any liquid from seeping into the equipment, for it will affect the safety and performance of electrocardiograph.

2) Patient Cable

- Integrity of patient cable, including main cable and lead wires, should be checked regularly. And be sure that it is conductible.
- Do not drag or twist the patient cable with excessive stress while using. Hold the connector plugs instead of the cable when connecting or disconnecting the patient cable.
- Align the patient cable to avoid twisting, knotting or crooking in closed angle while using.
- Store the lead wires in a bigger wheel to prevent any people from stumbling.
- Once damage or aging of the cable patient has been found, replace it with a new one immediately.

3) Electrodes

- Electrodes must be cleansed after use and be sure there is no remainder gel on them.
- Keep the suction bulb of chest electrode from sunshine and excessive temperature.
- After long-term use, the surface of electrodes will be oxidized because of erosion and other causes. By this time, electrodes should be replaced to achieve high-quality ECG.

CAUTION:

The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.

9 Warranty and Service Policy

9.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period. The warranty period begins on the date the products are shipped to distributors.

The warranty is void in cases of:

a) damage caused by handling during shipping.

b) subsequent damage caused by improper use or maintenance.

c) damage caused by alteration or repair by anyone not authorized by EDAN.

d) damage caused by accidents.

e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

9.2 Service Policy

All repairs on products must be performed or approved by EDAN. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair shall be exclusively be performed by EDAN certified service personnel.

If the product fails to function properly - or if you need assistance, service, or spare parts - contact EDAN's service center. A representative will assist you troubleshooting the problem and will make every effort to solve it over the phone or Email, avoiding potential unnecessary returns.

In case a return can not be avoided, the representative will record all necessary information and will provide a Return Material Authorization (RMA) form that includes the appropriate return address and instructions. An RMA form must be obtained prior to any return.

Freight policy:

Under warranty: the service claimer is responsible for freight & insurance charges when a return is shipped to EDAN for service including custom charges. EDAN is responsible for freight, insurance & custom charges from EDAN to service claimer.

Out of warranty: the service claimer is responsible for any freight, insurance & custom charges for product.

Contact information:

If you have any questions about maintenance, technical specifications or malfunctions of devices, please do not hesitate to contact us immediately.

Telephone: +86-755-2689-9221, 2689-9914

Fax: +86-755-2689-8330

Email: support@edan.com.cn

10 Accessories

10.1 Standard Accessories

⚠**WARNING**⚠: Only patient cable and other accessories supplied by EDAN can be used. Or else, the performance and electric shock protection can not be guaranteed.

Table 10-1 Standard Accessories List

Accessory	Part Number
Power cord	M13R-36014
ECG Cable (European)	MS1-106902-A0
ECG Cable (American)	MS1-107048-A0
Chest electrodes	M15R-040163
Limb electrodes	M15R-040162
Thermal recording paper	MS1R-107560-A0
Fuse	M21-64073
Rechargeable Lithium Battery	M21-064102

10.2 Optional Accessories

Table 10-2 Optional Accessories List

Accessory	Part Number
ECG Cable (European)	MS1R-107402-A0
	MS1R-110265-A0
ECG Cable (American)	MS1R-110375-A0
	MS1R-110266-A0
Pediatric Chest Electrodes	M15R-040168
Pediatric Limb Electrodes	M15R-040169
Input/Output connector	MS1-19907
Grounding Wire	MS1-20016
ECG Electrode	M15-40090
Pediatric Electrode	M15-40024
Neonatal Electrode	M15-40109
Smart ECG-Viewer	MS9-38952
	MS9-38953
Snap Clip	M15R-040172
Electrode gel	M50-78047
RS232 download Cable	MS2-20117
Ethernet download cable	MS2-20096
Smart ECG viewer Software Key/TINY-SPRO	M17-47116
Smart ECG viewer Software Key/ USB	M17-47194
DeskJet/HP2368	M18-52168
U disk	M50-78105

ECG bag	M50-78118
SD Card Reader	M17-047324
MT-201 Trolley	MS9-107058
MT-801 Trolley	MS9-107625
12V Vehicle-carried Inverter	M21-64056

12-channel electrocardiograph and accessories are available by contacting the manufacturer or your local distributor.

Manufacturer:

EDAN INSTRUMENTS, INC.

Address: 3/F - B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, shekou, Nanshan Shenzhen, 518067 P.R. China

Zip code: 518067

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11 EMC Information

Guidance and manufacture's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

<table>
<tr><th colspan="3">Guidance and manufacture's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The SE-1200 Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the SE-1200 Electrocardiograph should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The SE-1200 Electrocardiograph uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class A</td><td rowspan="3">The SE-1200 Electrocardiograph is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacture's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *SE-1200 Electrocardiograph* is intended for use in the electromagnetic environment specified below. The customer or the user of *SE-1200 Electrocardiograph* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2V for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T)	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *SE-1200 Electrocardiograph* requires continued operation during power mains interruptions, it is recommended that the

	for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	*SE-1200 Electrocardiograph* be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The *SE-1200 Electrocardiograph* is intended for use in the electromagnetic environment specified below. The customer or the user of *SE-1200 Electrocardiograph* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	$3V_{rms}$ 1 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *SE-1200 Electrocardiograph*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the

			transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *SE-1200 Electrocardiograph* is used exceeds the applicable RF compliance level above, the *SE-1200 Electrocardiograph* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *SE-1200 Electrocardiograph*.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the *SE-1200 Electrocardiograph*

The *SE-1200 Electrocardiograph* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *SE-1200 Electrocardiograph* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *SE-1200 Electrocardiograph* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.1167**	**0.35**	**0.7**
0.1	**0.3689**	**1.107**	**2.214**
1	**1.1667**	**3.5**	**7**
10	**3.6893**	**11.07**	**22.14**
100	**11.6667**	**35**	**70**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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